YALE MEDICAL LIBRARY
3 9002 08676 2409

END-STAGE RENAL DISEASE:
A METHODOLOGY AND LITERATURE REVIEW

MICHAEL HENDERSON OWENS

1978

YALE
אורים ותמים
MEDICAL LIBRARY

Digitized by the Internet Archive
in 2017 with funding from
Arcadia Fund

https://archive.org/details/endstagerenaldis00owen

END-STAGE RENAL DISEASE: A METHODOLOGY AND LITERATURE REVIEW

A PROFILE ANALYSIS OF A SELECT SAMPLE OF THE CONNECTICUT DIALYSIS POPULATION

BY

Michael Henderson Owens

A.B., Bowdoin College 1973

A Thesis Presented to

The Faculty of the Department of Epidemiology and Public Health
and the School of Medicine

Yale University

In Candidacy for the Degrees of

Doctor of Medicine and Master of Public Health
(Hospital Administration)

1978

Med Lib.
T113
Y12.
3798

Permission for photocopying or microfilming of "End Stage Renal Disease: A Methodology and Literature Review" for the purpose of individual scholarly consultation or reference is hereby granted by the author. This permission is not to be interpreted as effecting publication of this work or otherwise placing it in the public domain, and the author reserves all rights of ownership guaranteed under common law protection of unpublished manuscripts.

Signature of Author

5/16/78

Date

ABSTRACT

This thesis consists of (1) a literature review, (2) the development of a methodology for a profile analysis and (3) its subsequent application to a limited sample of the Connecticut End Stage Renal Disease population.

Attention is given to the equivocal role of the physician as manager of the patient care team, the role of allied health professionals in E.S.R.D. patient care, and the need for greater chart documentation.

DEDICATION

To my family for courage, the people for motivation and Jackie D. and Angie Manns.

TABLE OF CONTENTS

Page

ABSTRACT i

TABLE OF CONTENTS ii

INTRODUCTION 1

LITERATURE REVIEW

Medical Evolution 4

Policy Debate..15

The Legislation 22

Program Capability..28

Medical Review 31

METHODOLOGY

Background 37

The Instrument 41

Problems With Methodology 42

RESULTS AND DISCUSSION

Demography 44

Intake Parameters 45

Psychosocial Parameters and Initial Evaluation........46

Continued Professional Documentation 50

Dialysis Evaluation Parameters 52

CROSSTABS..58

COMMENTS AND RECOMMENDATIONS 87

FOOTNOTES 92

BIBLIOGRAPHY 98

APPENDIX..104

INTRODUCTION

The medical record, always the general chronologue of a patient's illness and his treatment successes and failures is assuming an important role as a medico-legal and routine quality of care assessment document. The assignment of the pivot role to the medical record is logical since there is no other widely utilized composite information source which details the daily management (professional and ancillary services report) and condition of the patients. Some problems arise from this assignment; however, i.e., the questions of accuracy and completeness. Inconsistent quality in either will militate against the validity of this instrument in assessing patient care.

Nonetheless, the importance of this document for quality assessment and cost control as perceived by the U.S. Legislature and the concurrence by the medical profession with at least the former role is underscored by the mandated 5 year retention of the medical record for adults and effectively greater than or equal to 3 years for minors by P.L. 92-603.

Chart documentation will logically reflect the nature and philosophy of a physician's medical education and training as well as any diploma and board certification evidence.

The need for an analysis of the Connecticut dialysis experience is aptly identified by the response of Network Coordinating Council No. 27's response to Network No. 3's criterion and standards final report.

> [1]"...It is clear that many networks will not have similar resources available to develop a comprehensive review system in a short time period. Nevertheless, we think it is critical to the meaningful interest and cooperation of our member units that a program such as the California project be developed on-site in the respective networks with the full participation of their members. Therefore, we are in agreement with the conclusion of the task force which stresses the necessity for locally developed criteria as a basis for the M.R.B. function. We also concur with the need for MRB unanimity in the criteria setting process."
>
> [2]"Perhaps the BQA would consider funding a second project here in Connecticut where we already have a registry in place and where the predominate setting of dialysis differs significantly from the Northern California."

The BQA (Bureau of Quality Assurance) recommends two ways for analysis of a given network's dialysis experience: Medical care evaluation (MCE) and profile analysis. The former entails the initiation and completion of an evaluation of patient care including criteria development and deficiency correction. The latter is meant to assist in problem definition and assessment of program effectiveness via analysis of aggregate patient data. This profile analysis (PA) should display patterns of health care services rendered over a specific time period. It is important to remember the PA can not be expected to provide definitive answers concerning the appropriateness on the quality of care, per se. This does not weaken its theoretical potential for problem identification and its significance as a methodologic starting point for any subsequent MCE study.

This thesis will consist of two major blocks; a literature review and a profile analysis of a select group of the Connecticut dialysis population.

The literature review presents the non-static history of the development of hemodialysis technology, the E.S.R.D. policy debate, the role of the federal government agencies in E.S.R.D. program capability evolution, a presentation of the legislation and a synopsis of program capability. An overview of the evolution of medical review and its role in cost and quality control is also herein presented.

The remainder of this thesis deals with (1) the instrument development for the profile analysis, (2) examination of its revelations and (3) my conclusions and recommendations.

LITERATURE REVIEW

Medical Evolution

The twentieth century, more so than any other in known recorded history, has been and will undoubtedly continue to be an explosive age of technologic innovation. This innovation has touched the "Western" world with greater discernible impact than much of the yet technologically undeveloped world. It has reached from its scientific cradle into the realm of philosophy and religion and consequently demands and challenges our abilities to incorporate scientific progress into previously established concepts of life, the value of life and morality.

The artificial kidney and renal transplantation represents the present zenith of the medical technologic progress and dramatically underscore the aforementioned challenge.

> [3]"Clinically, the artificial kidney machine is the first artificial substitute for a whole natural organ and kidney transplantation is the first surgical procedure for transplanting a whole natural organ from one individual to another."

The theoretical groundwork for the artificial kidney preceeded its present utilization as the professional mainstay for the treatment of patients with End Stage Renal Disease by more than fifty years. Many investigators, parallel scientific inquiries, and fortuitous discoveries, all figure prominently in the evolution of hemodialysis therapy. The discovery of Heparin in 1918, cellophane 1920's and teflon in 1938 and the Scribner Shunt in 1960,

all facilitated the practical application of the artificial kidney machine first developed by a Dutch physician, William T. Kolff, in Nazi occupied Holland in the early 1940's.

> [4]"The search for an artificial substitute in the form of an extra-corporeal machine dates most directly from the early part of this century. In November, 1912, John T. Abel, Leonard G. Rountree, and B. B. Turner, working at Johns Hopkins, performed an experiment that involved drawing blood from dogs, passing it by means of arterial cannula through a tubular "celloidin" semi-permeable membrane, and filtering diffusable substances from the blood back into the animal through a venous cannula."

> [5]"Kolff published his results in 1944, but Alwall in Sweden and Murray in Canada published results of clinical dialysis in 1947. All three physicians were working independently of each other and, until the appearance of Kolff's article without knowledge of each other."

The first artificial kidney machine built in America was called the Kolff-Brigham machine. Kolff supplied the engineering drawings from his machine to investigators at the Peter Bent Brigham Hospital in 1947. From the introduction of the artificial kidney into America until 1960, the machines were used extensively for treatment of patients with renal failure and to stabilize patients awaiting transplantation. Its usage was responsible for the differentiation of acute renal failure from chronic renal failure.

> [6]"The use of the artificial kidney from the late 1940's until 1960's led gradually to the distinction between acute and chronic renal failure."

The identification of chronic renal failure as a pathophysiologic entity and the development of the rudimentory apparatus for its palliation naturally generated considerable discussion within the medical, scientific, and lay communities concerning the applicability, reliability and dangers of hemodialysis.

Central to the heart of the debate was the question whether hemodialysis was in the experimental stage or could be considered established therapy. The leading investigators could often be quoted giving contradictory opinions on the progress of hemodialysis along what Rettig calls the experimental - therapeutic continuum. The question was not "authoritatively" resolved until 7 years after Scribner first revealed his shunt to the scientific community. The Gottschalk Committee stated in 1967 that dialysis and transplantation could be considered established therapies.

> [7]"Schreiner, Merrill, Teschan, Bleumle, Kolff and a few others were present. Schreiner, an editor of the Transactions had Scribner and his colleagues submit their three papers on their work. These papers were inserted and discussion presumably from the hotel room was included as if it were transcript of the questions and answers, and thus the news first appeared in the literature."
>
> [8]"In the debate on whether dialysis was experimental or therapeutic the Gottschalk Committee in its 1967 report can be regarded as the most authoritative statement that both dialysis and transplantation were to be regarded as established therapies."

The early days of dialysis could be characterized as somewhat tumultuous and the initial patients were instant celebrities. Greater familiarity with the technique of dialysis and its

dangers as well as increased appreciation for the pathophysiology of renal failure and its sequelae have lead to a more uniform approach to the management of patients with E.S.R.D. Numerous new and remodeled machines, dialysates, paraprofessionals, professionals and paraphernalia have contributed to the unequivocal emergence of hemodialysis as the predominent, if not preferred, method of treatment for patients with end-stage renal disease. As a consequence of the diligence of the aforementioned health care personnel, the survival of dialysands has increased significantly since the "early days," but no considerably greater increase in life expectancy is anticipated in the near future through improvements in dialysis technology. The small amount of money available for research and development of dialysis and transplantation therapies and technology relative to the total amount spent on E.S.R.D. patient care attest to the governments disposition and underscores the difficulty that is encountered by investigation interested in dialysis R and D.

> [9]"According to the National Institute of Health Data for fiscal year 1976, funding for research and development on renal failure, dialysis and transplantation amounted to 13.3 million which is only 1.5% of the amount expended in 1977 for care of patients with uremia."

Patients starting dialysis therapy dependent upon the etiology of their renal failure and the presence or absence of concomitant dialysis-related and non-related infirmity can expect

an 85-90% chance of survival at the end of 1 year, 60% survival at 5 years and greater than or equal to 35% chance of survival at 10 years. Equally important in predicting the survival of patients with E.S.R.D. is the mode of dialysis therapy which they receive.

Home dialysis has the best survival rate followed by facility dialysis. The difference in survival is greater in the first few years of treatment and decreases steadily as reflected by the end-of-year survival rates published in the February 16, 1978 NEJM shown in Figure I(e).

Paradoxically the percentage of patients on home dialysis has been decreasing consistently since the federal government started paying for dialysis treatment.

> [10]"Thirdly there has been a sustained decrease in the proportion of hemodialysis patients treated at home from 39.8% in 1972 (the year before federal assumption of the cost of dialysis) (Sic), to 23.7% in 1976. The DHEW has recently issued facility Report #2 analyzing Medicare-approved E.S.R.D. (...) suppliers for data available through December 31, 1976. This new analysis shows a further decline in the proportion of patients treated by home dialysis to 12.9% of all dialysis."

The reasons for this decline in home dialysis percentage is still unclear. A few variables do appear to be identifiable. One is patient willingness to be dialyzed at home and another is physician bias. Whereas most patients starting hemdialysis are quite ill, it is unlikely that they would readily respond to the idea of being dialyzed at home if they have been on center-based

(in hospital) dialysis for a considerable period of time, particularly if the option is presented too early in their therapy. Physician bias may be due to reimbursement schedules, the patients co-insurance provisions, allocation of their often scarce time, as well as the general movement of physicians in America away from the tradition of making house calls.

> [11]"It has become clear, however, that the fraction of uremic patients on dialysis at home reflects physician bias rather than regional differences in patient population. In Japan for example, where nephrologist have opposed home dialysis, only 103 (0.6%) (Sic) of 18.010 patients on hemodialysis in July, 1977 were being treated at home. By contrast, 66% of all hemodialysis in the U.K. where the uremia budget has a specific allocation, is performed at home. Similar disparities exist in the U.S. where more than 75% of patients on dialysis in the State of Washington and 60% of patients in Indiana receive this treatment at home at the same time that fewer than 15% of patients in the Northeast perform self-dialysis."

The increased survival of patients with E.S.R.D. being treated by dialysis has resulted in a greater awareness of the sequelae of E.S.R.D. as well as the sequelae of its treatment. These sequelae may include complex endocrine, hematologic and neurologic problems to categorize a few.

> [12]"The several complications of renal failure and its treatment are recognized: atherosclerosis may be accelerated, hypertension, anemia, osteoperosis, increased susceptibility to infection and gastrointestinal disturbances. Neurologic abnormalities - both central and peripheral are not uncommon."

It is presently difficult to determine the "state of the art" concerning dialysis outcomes relative to treatment and to determine whether present and potential therapies will impact on

patient survival, mode of therapy and resource allocation for patients with E.S.R.D. This difficulty arises from the fact that there is no national dialysis registory at the present -- hopefully, the bureaucracy will resolve this "temporary" inconvenience.

> [13]"Until 1975, a record of about 85% of treated patients was kept by the National Dialysis Registry under contract to the Artificial Kidney - Chronic Uremia Program of the National Institute of Arthritis, Metabolic and Digestive Diseases. Transfer of the responsibility to the Social Security System in late 1975 has resulted in a hiatus in reporting data on both transplantation and patients on dialysis to the extent that figures for the current year are unavailable."

RENAL TRANSPLANTATION

Hemodialysis although presently the predominent mode of therapy for patients with E.S.R.D., is not the only noteworthy method of therapy available. Renal transplantation has been developing simultaneously with renal hemodialysis, dating back to the procine heterograft experiments in 1950's and evolving to the comparatively greatly sophisticated HLA matching system utilized today. The most significant breakthrough in renal transplantation to date is the ability to mollify the rejection reaction through the use of ummunosuppressive drugs which were initially used in 1963, and have been the vanguard for salvaging cadaveric transplants.

> [14]"In 1963, it was realized that the use of immunosuppressive drugs could aid in the immunologic rejection problem confronting transplants that involved a cadaveric rather than a living - related kidney."

Subsequent to the initial use of immunosuppressive drugs and the transplant surgeons' increased familiarity and expertise, there was an appreciable decrease in patient mortality particularly for cadaver - kidney recipients. A smaller but appreciable decrease in living related-donor recipients mortality was also observed.

There is presently and will continue to be much debate over whether renal transplantation represents optimal therapy for patients with E.S.R.D. It is unequivocably better therapy than dialysis as it relates to the "quality of life" whereas many of the successful recipients are able to return to normal lives with the help of medication. Transplantation, however, is not for everyone. The elderly have an increased risk of mortality and morbidity, elderly females more so than males.

> [15]"The significant decline in patient mortality (p .001) from 57% in the earlier period to 23% after 1968 demonstrates improved treatment of complications and increased use of dialysis. This decrease in mortality is noted especially among recipients of cadaver allografts,..., although it occurred among those with living related grafts."

> [16]"An analysis of mortality as dependent upon age and sex showed that females receiving living related kidneys in their 5th decade were significantly (P=0.016) (sic) more at risk than males of comparable age or than patients of either sex in younger groups (P=0.01)."

Hemodialysis survival curves lie between the corresponding curves for living related donor recipients and cadaveric donor recipients and the therapies are considered to be supplementary

therapies instead of competitive. Patients should be educated to consider them part of a total potential package, given the noteworthy but poor graft - survival rates for cadaver transplants.

Information on total number of patients receiving each method of therapy and their relative survival rates are given in Figure I Tables a-e, and Figures II, III.

> [17]"It seems increasingly clear that, as the experience in both dialysis and transplantation accumulates, they must be used conjointly as part of a total treatment for those with End Stage Renal Disease, with transplantation acting in relation to dialysis in a complimentary rather than a competitive manner."

RENAL DIALYSIS IN CONNECTICUT

Literature on the Connecticut dialysis experience is scarce. The Connecticut experience varies from that national experience in a few noteworthy ways. Similar to the national experience the majority of patients in Connecticut are receiving in-center dialysis; however, the literature available suggests that the percentage of patients being dialyzed at home was increasing. The information available, unfortunately, addresses the 1966 to 1972 time period (prior to federal assumption of the cost of dialysis) and is not directly comparable to the data presented by E.A. Friedman in the previously referenced NEJM article. See Figures I(b) and V(a).

> [18] "By far the greatest percentage of patients received in-center dialysis (over 83% between 1966 and 1972) (Sic.) As of November 1972, there had been an increase in the percentage of patients dialyzed at home; the percentage increased from 16.4 over the study period to 21.7."

Consistent with the national dialysis experience and the general patterns of the national health care delivery experience, the majority of hemodialysis services are concentrated in the urban areas and fewer patients live in the rural areas where fewer treatment units are located. See Figure V(d).

> [19] "Almost 1/3 of all the units are in the South Central HSA, which contains the Yale - New Haven Medical Center/Veterans Administration E.S.R.D. Program; the largest number of individual treatment units, 14 are at the West Haven VA Hospital."

The demographic breakdown of the Connecticut E.S.R.D. dialysis experience differs from the national population. Sixty percent of the 353 patients reported by Pearson, et.al. were male and 40% female. The Ethnic categorization of the Connecticut population revealed about three time the number of non-European American patients as there were known to be residing in the state. But consideration of the validity of this 3 to 1 ratio must take into account the vagaries of census taking. See Figure V(6).

> [20] "A comparison of the Connecticut dialysis patients with those on the National Dialysis Registry shows that the State has a smaller percentage of males in chronic dialysis programs."

> [21] "Nineteen percent of the total patient population and 22 percent of the active patients were non-white. This non-white caseload of both total and active patients appears high compared with Connecticut's 1970 non-white population of only six percent."

Contrary to the national norm (prior to the federal assumption of dialysis cost), Connecticut also was in the enviable position of having adequate dialysis facilities when assessed on a per million population basis. The dialysis population of the State has increased by almost forty-five percent from about 350 to about 500 since then. The picture is not as clear whenever dialysis centers in one HSA now have to refer patients to those in others. This problem largely results from the continuation of the established treatment modality patterns in the State. If the tendency toward center based dialysis treatment continues, Connecticut will inevitably and unnecessarily encounter the same shortage problem as other States.

> [22]"Hollen and Harris estimated the number of annual potential hemodialysis patients in the 15-54 year age group to be between 67 and 84 per million population. Because the number of new patients entering Connecticut programs during the first 11 months of 1972 (131 or 79 per million) (Sic) is consistent with the Hollen and Harris estimates. It is suggested that Connecticut is in the unique position of providing adequate services for the population in need."

> [23]"Connecticut therefore, is probably one of the few States where hemodialysis services are not in short supply, given the claims regarding the national lack of hemodialysis services."

Connecticut's dialysis patients as the rest of the nation's fare poorly with respect to the percentage receiving renal transplantations however. The problems have the same etiology, and insufficient number of cadaveric donor kidneys consequent to an

increasing demand and un unequal increase in supply. The problem(s) is likely to get worse before it improves whereas increasing numbers of critically ill and previously marginally or totally unacceptable patients are being hemodialyzed. Physicians now have little rationale to prevent attempting to improve the survival and/or quality of life of any patient who might benefit from dialysis therapy.

> [24]"It was found that the percentage of patients removed from dialysis through renal transplantation declined, however, the absolute number of transplants increased. This appears to be an indicator that renal transplantation has not kept pace with the increasing dialysis population."

The Policy Debate

The policy debate concerning E.S.R.D. centered around two points; the position of dialysis along the experimental-therapeutic continuum and the role of the federal government in financing patient-care.

The location of a new medical procedure along the "continuum" logically had a considerable impact upon the policy debate concerning the role of the federal government in the regulation of that procedure as well as the role of the medical profession in its practice. Practitioners logically might consider rapid implementation of such a life-saving procedure as prudent for their patients. The more research oriented physician logically

might stress the limitations of knowledge and the shortcomings of "half-way" technology, recalling the inadequacy of the iron lung vs. vaccine for polio. As a result of his advocacy of the technique Scribner was not invited to the N.I.H. Conference in November, 1964, and held his own.

> [25] "Consequently, among clinical investigators 'the Scientist' is likely to emphasize the unknowns and uncertainties of a new procedure, to stress the limits of knowledge, and to regard it as experimental for a longer time than a 'physician'. By contrast, the 'physician', is likely to emphasize the prospective benefits of a new procedure and de-emphasize the associated uncertainties."

> [26] "For example, in 1969, a Medical Advisory Board was created within the National Kidney Foundation in large measure to offset the research influence of the scientific community. As another example of the dissatisfaction in the early 1970's with ASAIO at the limited portion of the agenda located to dialysis and renal transplantation led to the establishment of the Council on Dialysis and Transplantation. This free floating group later attached itself to the National Kidney Foundation."

A combination of legislative and administrative forces before and after the adjudication that dialysis and transplantation were established therapy by the Gottschalk Committee in 1967 attempted to limit the role of the federal government to facility support or no support.

> [27] "However, the Senate, in setting forth the legal authority for P.H.S. action, limiting the scope of that action to demonstration and training, and providing modest funds for fourteen community dialysis centers reflected great reluctance to accept federal government responsibility for paying the cost of treatment."

> [28] "The Health Service and Mental Health Administration, under whose authority the Kidney Center Program was then being administered, took action to terminate grant support."

The influence of "identifiable lives" played a literally conspicious role in the "debate." The 'drama' of dialysis before the House, Ways and Means Committee attest to the unique stature of patients with E.S.R.D. Particularly when the fact that numerous more Americans are afflicted with other debilitating illness, i.e., hemophilia, where optimal treatment can cost virtually prohibitive amounts.

The debate on payment for treatment of E.S.R.D. transpired concomitantly with the greater debate about the role of the federal government in the financing of health care services. The unique medical status of E.S.R.D., and its proposed program were thought to present an opportunity for "small" scale experimentation to test the administrative capability of the federal government to gear up for and implement a catastrophic and/or National Health Insurance Program. Both programs were and are known to have strong legislative leadership backing most notably by Senators Russel B. Long and Edward M. Kennedy, respectively.

> [29]"It should be remembered that Senator Russel B. Long, Chairman of the Senate Finance Committee, was then, and now advocating health insurance for catastrophic illness.... Therefore, in addition to being included under the general language of the disability provisions, financing of treatment for E.S.R.D. was also seen as the first step toward providing catastrophic medical insurance through Medicare."

The Medicaid/Medicare experience of continuously escalating cost and flagrant abuse also figured prominently in the "debate." Whereas about ninety percent of patients with E.S.R.D. were

eligible for benefits, the private market was essentially removed as a benchmark for evaluating the reasonable cost or charges for treatment. The program planners were eager to implement the program in a manner which would restrict, if not temporarily prevent, a sudden increase in the number of facilities providing services on the eve of the creation of another guaranteed patient market.

> 30"The emergence of cost control as an objective of regulation is attributable to several factors. The entire 1972 legislation was permeated with a desire to control the cost of Medicare which had continuously escalated since its enactment in 1965. Since the E.S.R.D. program established nearly universal coverage for kidney failure the private market was essentially eliminated as a basis for determining the 'reasonable cost' and 'reasonable charges of treatment'."

The threat of litigation has significantly hampered the establishment and operation of a bureaucratic mechanism for implementing cost control incentives. Potential review cases are often adjudicated in favor of the providers by DHEW because of the desire to avoid lengthly, costly court battles. Potential litigation will also unfortunately be an impediment to the establishment of a National Health Insurance program. The reticence of the government to pressure all suspected offenders underscores the position of cost control as a secondary objective of the E.S.R.D. program; its primary intention being to provide medical services to the population in need.

The secondary nature of the government position notwithstanding, some cost control provisions were an inevitable part of the final legislation and understandably so. The health care industry is now the number two industry in the country and the government provides greater than fifty cents on the dollar of the total expenditure. The nature of the cost control provisions were another topic for considerable discussion and bureaucratic "jawboning" with various federal agencies attempting to protect their respective turfs and modi operandi.

> [31]"Bureaucratic competition and conflict between the SSA's BHI and the office of the Assistant Secretary for HEW will strongly affect cost control design. BHI is likely to favor cost control mechanism which incorporate administrative simplicity and maximum consistency with the existing Medicare procedure. The office of the Assistant Secretary is more likely to be concerned with an overall cost control strategy though it is also susceptible to the representation of other interests."

> [32]"Between 1969 and 1976, total annual expenditure for health care in this country increased from the 64 billion to 139 billion."

The nature of E.S.R.D. is that it strikes without reference to barriers of sex, age, race or geography and would, ideally, not arouse wide-spread claims of political favoritism from most legislators' constituencies. The potential for rehabilitation and subsequent gainful employment of patients with E.S.R.D. helped make the macroscopic economic cost considerations more pallatable. Whereas the issue was being "debated" at the same

time that the performance of therapy was improving, it was argued that the cost were not unreasonable and that the unit cost of treatment was improving.

The economic consideration were not reliable estimates of the unit or aggregate cost of therapy for several reasons. Initially patient selection criteria were more severe than at present. Limitations on age were applied at both ends of the spectrum and limitations on the types of patients were also applied. Once the question of financial resources was removed as the final arbiter of the distribution of scarce medical technology, physicians had few reasons for denying therapy to anyone who might benefit.

Approximately 10,000 new E.S.R.D. patients, more than double that before passage of the 1972 Law, enter the system annually. Approximately 3,000 are transplanted about 1,800 successfully and the rest return to dialysis each year. All of these factors contributed to the miscalculation of the potential aggregate cost for treatment of patients with E.S.R.D. Inflation has similarly invalidated previous unit cost estimates.

[33] "As of June, 1975, there were 21,800 people enrolled in the Medicare E.S.R.D. program; by September 30, 1975, the number had increased to 24,000 (both transplant and dialysis patients are included in this number) (Sic). By 1980, it is expected that 50 through 60,000 people will be receiving Medicare benefits under the E.S.R.D. (Sic) program."

The legislative history of the bill was not very conspicous except in its near absence. All of the legislative action was via the appropriations committee and no hearings were held from 1965 to 1969 on any pertinent legislation. The Gottschalk Committee did recommend E.S.R.D. patient care financing through an amendment to Title XVIII of the Social Security Act in 1967. The legislative action was not taken until 1970 when the legislature amended the RMP's authority to include kidney disease and the DHEW's P.H.S. - Chronic Renal disease program was effectively terminated, legally and administratively.

Neither the Senate nor the House heard testimony on E.S.R.D. during the hearing on H.R.1 although the House Ways and Means Committee heard testimony in late 1971 urging the inclusion of E.S.R.D. in any national health insurance program. There was no activity within the Senate Finance Committee dealing with E.S.R.D. and the Conference Committee between the House Ways and Means Committee and the Senate Finance Committee met for a single day. The kidney amendment received only ten minutes discussion and was passed without significant moderation. The federal government through its demonstration and capacity building, research and development, as well as the acceptance of financing for eligible veterans essentially created that which many of the legislative and administration policy makers initially tried to avoid.

[34] "The End Stage Renal Disease amendment was not considered until the provisions of the entire H.R.-1 bill were being debated seriatim on the Senate floor. On a Saturday morning, hardly a normal legislative work day, September 30 barely 1 month before the November election, Senator Vance Hartke (D-Ind.) was recognized at 11:30 AM to propose an amendment on chronic renal disease. Thirty minutes of time was allocated to the immediate consideration of the Kidney Amendment."

The Legislation

The E.S.R.D. program became effective on July, 1973 and until the final regulations of June 3, 1976 was operated under Interim Regulations which were published and republished on 6/29/73 and 4/22/75, respectively. The first interim regulations provided for reimbursement to facilities administering E.S.R.D. care on/or before 6/1/73, and describe criteria for reimbursement for expanded or additional facilities during the interim period. The second interim regulations proposed rules in areas relating to (1) qualification for Medicare reimbursement, (2) minimal utilization rates, (3) supplier certification, (4) network designation, (5) establishment of network coordinating council (NCC) and medical review boards (MRB's).

In the absence of the MRB's, the Interim program through the initial Intermediary Letter issued by the Social Security Administration (SSA) sought to eliminate unnecessary services in the use of laboratory procedures and physician services for stabilized patients. Office visits for stabilized patients were limited to

one per month and extensive examinations to two per year. One of the most discussed features of the Intermediary Letter was the initial requirement that physicians be paid out of facility reimbursement funds. This idea created a plethora of opponents and was consequently modified to include the aforementioned option and to permit physician reimbursement directly or on a retainer basis. The choice was left up to the determination of individual groups of physicians associated with a given facility.

The Interim regulations specified that no assurance of long term approval was guaranteed by interim period recognition of a facility and that facilities not qualifying under the long term final regulations would be curtailed in a fashion which would minimize disruption of services to E.S.R.D. patients.

The general intent of the final regulations was: to assist dialysands to receive the required care; to encourage proper utilization and distribution of resources so as to maintain adequate or improved quality of care to patients with E.S.R.D.; and to allow the flexibility necessary for physicians and facilities to provide appropriate care.

The final regulations established 32 E.S.R.D. networks, 26 of which had a base population greater than or equal to 3.5 million. E.S.R.D. network designation was made primarily according to S.M.S.A. analysis attempting to preserve their integrity and

recognize patient referral patterns for transplantation and patient flow patterns. Each "network" was to have a Network Coordinating Council (NCC), as well as a Medical Review Board (MRB) and the extent practicable be coterminus with HSA and PSRO's.

The network coordinating council membership as elaborated in the final regulations must include: a transplant surgeon; a nephrologist, a social worker, a chief executive officer, a qualified dietician, a director of a histocompatability lab, a director of an organ procurement agency, 3 informed consumers and a qualified nurse. If the NCC has greater than twenty members then an executive committee (better than 25% consumer) of less than or equal to this number must be formed to assume the responsibilities of the council.

Each E.S.R.D. network's facilities must collectively include the capability for chronic dialysis, self-care dialysis, transplantation (at least two transplant centers per network), center based dialysis, organ procurement, histocompatability testing, and supportive services for home dialysis.

In order to qualify for reimbursement each E.S.R.D. facility must: belong to a network; have executed an agreement with the NCC; have the mandatory staff; and, be able to provide back-up services on a twenty-four hour basis. The mandatory staff are chief executive officer, clinical social worker, clinical nutritionist, medical record practitioner and a physician director. Other

personnel are considered staff but are not defined by the final regulations and I refer you there for further elucidation. (See Appendix)

The responsibilities and duties of the NCC are myriad. The more salient are: (1) the appointment and monitoring of the MRB (composed of 7 members), (2) the development of written arrangements with Professional Standard Review Organizations (P.S.R.O.'s), (3) the description of a mechanism for development of prioritized criteria and standards by the MRB, (4) the development of written working arrangements with HSA's and SHCC to assure that these organizations receive appropriate advice concerning needs of E.S.R.D. patients within their jurisdictional boundaries and (5) the provision of a mechanism for the inclusion of the opinions of others not on the MRB who have expertise and/or interest in procedure development but who are not qualified for Board membership by discipline category or simply not currently serving on the Board.

The majority of NCC's have undertaken the appointment of the MRB but it is still too early to expect much more progress in the elaboration of specific criteria and standards by these fledgling organizations.

> [35] "The majority of the NCC's have begun to appoint their MRB's in accordance with the final regulations, and all are expected to be approved by July 19, 1977. In a few instances, the MRB's are functioning under earlier arrangements with various organizations (e.g., State Kidney Council) and all should be involved in developing their plans for medical review by mid-summer."

The salient responsibilities of the NCC appointed MRB's are: (1) to develop written arrangements with P.S.R.O.'s, (2) to develop a mechanism for measuring mandatory long term patient care effectiveness, (3) in concurrence with the NCC to coordinate the performance of medical care evaluations, (4) to provide facilities and physicians written recommendations for improvements on the E.S.R.D. in the care of individual patients or groups of patients based upon its review processes, (5) to provide all facts concerning the continued delivery of inappropriate or substandard care to the council and secretary.

The cost of the MRB and NCC operation is to be borne by the Secretary of HEW; it should be emphasized that network organizations are not to be charged with the enforcement of federal, State or local statutes and that the legal jurisdiction is unaffected.

The NCC's and the MRB are the network-wide agents to assure the quality of care for patients with E.S.R.D. There are numerous facility and personnel related facets of the legislation aimed at ensuring quality of care; continuing education, JCAH inspection, participation in medical information systems, provisions for independent histocompatability lab testing, provisions for approving new facilities, regulation of affiliation agreements or arrangements among other medical care programs. Detailed discussions of the above can be found in the copy of the final regulations in the appendix.

No discussion of the E.S.R.D. legislation would be complete without a synopsis of the benefits and immediate safeguards for the dialysands whose needs the legislation attempts to serve. The first consideration, who is entitled to benefit, is clearly specified in the final regulation of the legislation.

> [36]"Sec. 2991 of Social Security Amendments of 1972 P.L.(92-603) which extends Medicare protection to any individual who has E.S.R.D. requiring dialysis or transplantation, provided that such individual is: (1) fully or currently insured or entitled to monthly benefits under Title II of the SS. Act; or (2) is the spouse or dependent child of an individual so insured or entitled to such monthly benefits."

The coverage stated above is ubiquitous protection whereas the patient is not precluded from receiving his/her care in a network facility outside the network in which he/she resides.

The focal organizing point of the patient's management is called a patient care plan (PCP). This plan is an individualized therapeutic approach developed by the attending physician, the nurse supervisor, as well as a qualified social worker and dietician which reflects the functional, psychological and social needs of the patient. The patient or legal guardian is to be involved in the development of this Patient Care Plan and the patient's preferences, sense of dignity, individuality, private and personal needs including but not limited to provisions for translators when appropriate are to be given due consideration. A team coordinator is to be appointed by a physician. The coordinator is to ensure that review conferences are held and that changes in the P.C.P.

are recorded and that progress notes are incorporated into the patient's records at least monthly.

> [37]"In addition, it is stated that each patient must be evaluated in the long term not less frequently than every 12 months. The review of the patients program in the patient care plan must not be less frequent than monthly; a comment that this evaluation be made not less frequently than twice monthly was believed to be more frequent than necessary for most patients."

Other salient benefits of the legislation include provision for enrollment of patients in the cadaver recipient registry as well as clearly stipulated protection of the confidentiality of his/her medical record. Presently, attempts at rehabilitation are left up to the discretion of the provider facility.

Program Capability

The pioneers in program development for patients with E.S.R.D. were the founders of the presently named Northwest Kidney Center. Numerous factors enabled this Seattle, Washington based organization to assume the early leadership role in program development. See Figures VI-VIII.

> [38]"Discussions began in 1960 and culminated in 1962 with the creation of the Seattle Artificial Kidney Center, now the Northwest Kidney Center (NKC). Important to this development was the view of Scribner that a clinical treatment facility was needed in Seattle, and the position of the University of Washington which was bearish on expansion of its Hospital for dialysis purposes. Also critical was the exercise of leadership by Dr. James Haviland, President of the King County Medical Association, a former president of the American College of Physicians, and a moving force in organizing a single dialysis center for the city.... Also essential was the establishment of community fund raising for the center and a grant from the Hartford Foundation. This provided a financial base independent of the federal government."

The leadership role of the Seattle group was not limited to the development of the NKC. From shortly after the inception of the NKC a number of young, patient care oriented physicians traveled to Seattle to learn how to perform dialysis. A number of the physicians who were subsequently instrumental in the V.A. and Public Health Service dialysis effort also traveled to Seattle to learn about hemodialysis.

The V.A. was not hesitant to follow the Seattle lead and in 1963 announced plans to establish dialysis unit in thirty of its hospitals. This program resulted in the V.A. programs dialyzing about 16% of the total reported dialysis population by 1972. It was the V.A. program that was instrumental in the formation of the Gottschalk Committee. These V.A. programs became eligible for E.S.R.D. network membership consequent to a memorandum of understanding between DHEW and the V.A.

The DHEW via its member agencies and institutes was initially less enthusiastic about becoming involved with dialysis program research and development. It became involved in 1964 largely as the result of action taken by the House and Senate Appropriation's Committees. Consequently, the Transplant Immunology Program within the NIAID and Artificial Kidney/Chronic Uremia Program with NIAMD were established in 1964 and 1965, respectively.

> [39]"In 1963, fully 2 years before the establishment of the AK/CU program of NIAMD and the Kidney Disease Control Program in the PHS, the V.A. Announced its intention to establish dialysis centers for eligible veterans in 30 V.A. hospitals around the country. It was, in fact, a request from the V.A. to the BOB (Sic) in 1965 for authorization to use construction funds that set in motion the establishment by the BOB of the Gottschalk Committee to review the implications of treatment for End Stage Renal Disease for the nation as a whole."

In 1968, when the Kidney Disease Control Program was transferred from the PHS to the RMP's, dialysis capacity building largely supplanted demonstration projects. This transfer and the consequent decentralizing of project funding was substantially responsible for the capability of the medical community to provide services to the increase in patient population consequent to Medicare funding.

The aggregate and unit cost of maintaining the E.S.R.D. program that evolved from the aforementioned program development has continued to increase. The Twelfth Renal Transplant Registry published in 1975 states that the therapy of conventional uremia will cost $902 million in 1977 and $2.3 billion in 1982 to treat about 37,100 and 55,900 patients, respectively. These latter figures are considered conservative because of increasing attempts to dialyze more medically ill patients. The most recently estimated figures are those presented by Stange, et.al. in the February 16th issue of the NEJM which are basically consistent with U.S.G.A.O. recently updated unit figures (See Figure IX). The article also gives a rudimentary cost/benefit projection.

[40] "It is predicted that if 1000 patients shift from facility to home dialysis for each of 10 years, life expectancy of the cohort will not be reduced, but there will be a reduction of $241 million in the total cost. The same number shifting from facility dialysis to cadaver transplantation are predicted to have a $279 to $330 million reduction in total cost but a reduction of 7 to 17 percent in life expectancy. Shifting from home dialysis to transplantation is predicted to reduce total cost by $103 million, and life expectancy by 10 to 20 percent."

Medical Review

Florence Nightingale is generally accredited as the Mother of systematic medical review. Professor Thompson can readily recall stories of her revolutionizing the sanitoriums of her era as the result of her organized observation and analysis. This 19th Century pioneering effort in the use of systematic analysis as an adjunct to clinical judgement to optimize patient care put her a step ahead of her contemporaries. Most of them were utilizing their independent judgements and consciences to regulate the quality of care they delivered.

The landmark Flexner report published in 1910 brought the question of quality of care into the twentieth century and into the public limelight by asserting that much of the available medical education was inadequate and that it was producing numerous physicians of substandard quality. The tempo was not to slow down and Dr. E.A. Codman opened his "end result" hospital in 1912. He faithfully abstracted his patients charts and analyzed the data to review their treatment. The work of these early 20th

Century clairvoyants helped result in the eventual creation of the J.C.A.H. This organization has been a powerful force in the maintaining of structural quality of care assessments even through the expansionist period that came about as a result of Title XVIII and XIX of the SS Act.

> [41] "Influenced in part by Codman's system and Flexner's report the American College of Surgeons was formed in 1913. Initially, the American College of Surgeons planned to review or evaluate specific 'process criteria' (i.e., procedure and activities) (Sic) for common surgical operators, but the organization's review chose 'minimal standards' focused primarily on the structural and organizational aspects of the hospitals."
>
> [42] "The American College of Surgeons was succeeded by the J.C.A.H. in 1952 as the organization providing systematic review of hospitals."

Concomitant with the stipulation that eligibility for Title XVIII and Title XIX reimbursement funds were contingent upon J.C.A.H. or the appropriate state agency approval, the 1965 legislation also required establishment of a utilization review. This review program laid the foundation for utilizing outcome parameters as well as structural criteria and resource use for the evaluation of the quality of care of patients covered by the 'Act.'

Quality of care assessment is still in the infantile stages of development in the U.S. There is little agreement among provider professionals concerning whose definition of quality is to be applied and whether the parameters being evaluated at present have statistical validity. Nonetheless, the task of criteria and standard development as mandated by law lumbers forward. It should be noted that process measurements are also being developed.

> 43"There exist a paradoxical situation, in which policy demands that operational quality assurance systems use the outcome method to assess quality of care, while there is a dearth of valid and reliable outcome criteria and standards and no method or proven feasibility by which they can be applied."

> 44"Although the desired result from medical review is improvement in the outcome of patient care (e.g., patient health status, patient satisfaction, and patient commitment), the validity and usefulness of outcome criterion when used alone are questionable."

The above considerations notwithstanding, professionals continue to strive to elaborate the requisite methodology to comply with the federal legislation. A few considerations have gained some acceptance as central to the successful consensus formulation of any quality assurance system. Amongst them are: (1) selection of a qualified priority setting team, (2) a formal mechanism for solicitation of professionals' ideas and judgement and (3) a formalized data sheet to gather an adequate information base.

> 45"The structured quality assurance topic selection procedure recommended in this report consists of 5 major steps: (1) the selection and organization of the priority team, (2) the training session, (3) the incubation period, (4) the priority setting meeting, and (5) the selection of topics for implementation."

The Medical Review Board of each network has the immediate responsibility for establishing a network wide quality of care program as previously stated. Topic selection is an integral part of this legislative charge to the M.R.B.'s. The legislation

gives the M.R.B.'s Carte Blanche in topic selection stating simply that problems identified by the National E.S.R.D., M.I.S., state agency reports or the catch-all referred to as "professionally perceived problems." The purpose of such latitude is to ensure that mechanisms and plans for each network will be able to reflect any local geopolitical or environmental pecularities of that network which will cause local standards to vary from the "national norm."

Various approaches to medical review are recommended by the BQA for M.R.B. considerations.

> [46] "Various approaches to E.S.R.D. Medical Review...The areas in which the network needs to consider various approaches are the following: (1) network-wide and facility based reviewing, (2) interdiscipline and single discipline review; (3) and ratification."

The most ambitious attempt to elaborate criteria and standards is the No. California and Nevada Network #3 undertaking. This undertaking is an exemplary demonstration of the format proposed by Williamson in the February 15, J.A.M.A. The authors steadfastly emphasize the need for unaminity in standards and criterion setting as well as their reservation about applying the California standards and criteria to other networks. One must still be carefully critical when evaluating the criteria and standards elaborated by Committee and the consensus method.

> [47]"Committees may generate guidelines that recommend what should be done in an ideal setting rather than what is feasible to an active practice. Consensus may be impossible to obtain and rarely does the literature yield enough well designed studies to help resolve conflicts. The end product of the time consuming task of developing explicit criteria often reflects the judgements of those to be evaluated and may be as arbitrary as implicit standards."

The legislative regulations (by allowing for participating of any concerned party in the identification of problem areas) does have theoretical safeguards against the creation of "flim-flam" criterion and standards.

> [48]"The Council of the Secretary may initiate a request for information from the board under the following circumstances: (a) the identification of a possible problem area through the E.S.R.D. M.I.S. Survey Report Form, Fiscal Intermediary reports, on medical review reporting activities. (b) the identification of a possible problem area through individual or group inquiries to the council or the secretary.

There are three problems which lie at the heart of any attempt to develop criterion and standards which must be assessed in any consideration of methodology based upon medical records. The first is diagnostic specificity and the second is the participation of physicians in filling out the necessary forms which will inevitably be developed to assist in the assessment of the quality of care and the third is the difference between chart documentation and the actual practice of medicine.

In essence, the banner has been given to the medical profession. It has been told 'brethern heal thyself' by the legislature. It has been told that society believes the profession

best suited to do the job and to develop a system of ongoing surveillance. It has also been told "or-else" and to this end we will now proceed to the methodology for this study.

[49] "Another common problem, diagnostic specificity, became apparent when the medical records of more than 1,100 patients with hypertension were reviewed. Approximately 800 were under treatment for hypertension, but a specific diagnosis of essential or primary had been made in less than 10% of these patients."

METHODOLOGY

Background

The background of the development of the methodology of this study had a considerable impact on (1) its final structure, (2) the limitations of the amount of data gathered, and (3) the generalizability of the information gathered by its application.

The scenario includes four "independent" parties: myself - the "naive" student; Professor John D. Thompson - my research advisor and Director of the Health Services Administration division at the Yale School of Public Health; Frederic O. Finkelstein - M.R.B. Chairman for Network #27 and Director of the Yale-New Haven Dialysis and Transplant Service and; Ms. Jenny Kitzen - Executive Director of the E.S.R.D. Program for the Network and former Social Worker for the YNHH Unit.

The instrument utilized (See insert M-1 in the appendix) was ready for data collection in November of 1977 shortly after Ms. Kitzen and Dr. Finkelstein assumed their network positions and consequently prior to the network's readiness to undergo any data collection. I was unable to start data collection until January 1978 and was not finished until March 1978. The delay in data collection resulted from varying philosophies about the logical starting point for assessment of the quality of care of patients receiving E.S.R.D. services in Connecticut as well as concern over potential completion for subsequent project funding.

Several brief meetings between myself and Dr. Finkelstein and/or Ms. Kitzen and ultimately between all four concerned parties were held to discuss the two major approaches to the problem that were being considered. Dr. Finkelstein and Ms. Kitzen expressed the belief that the network already had a good idea what the problem areas were/are in the management of the Connecticut dialysis population. Consequently, they favored soliciting opinions, developing instruments and gathering data in a problem-specific manner. Professor Thompson and I were/are of the philosophy that although investigation into these "professionally perceived problem" areas might be beneficial a more logical starting point would be to determine a baseline for documented services offered to the Connecticut population and utilize it to help identify whether any problems existed.

These meetings concluded without any real compromise of our respective positions. Nonetheless, it was agreed that Professor Thompson would draft a letter to be sent out under joint signatures to all the facilities in the network (see M-2 in the appendix). This letter was never sent because the network representatives felt that it implied that "recognized standards" were to be applied to a sample of patients' charts and they felt that no "standards" existed. I was also emphatically informed that it was the domain of the M.R.B. to elaborate criteria and standards. The argument that the literal criteria and standards elaboration

is the domain of the M.R.B. is irrefutable. The legislation unequivocally expresses this intent. The problem with respect to this letter arose largely because of semantic but nonetheless real and apparently important disagreement.

The result of this impasse was that I was consequently unable to visit all of the dialysis facilities and take a twenty percent sample of their populations as hoped. The discussions and delays consequent to the need for the N.C.C. to be continously and logically appraised of our discussions resulted in the sample being changed to a forty percent sample of half of the dialysis facilities. This turned out to be impractical because, at this point, I was under considerable time constraints to get the study moving (1) because the funds were available for me to do it and the finished product had been promised for May delivery (see M-3 and M-4), (2) my thesis deadline was rapidly approaching and (3) I encountered considerable amounts of lag time between being informed what facilities it would be most easy to access and the actual time I was able to get the requisite appointments and clearance by the various facilities.

I mentioned earlier that money was a factor in the deliberations. It was so in two ways: First, there was considerable confusion regarding the source of the money to do the study. I initially submitted a request for funding to both Professor John D. Thompson from his RMP grant and from the E.S.R.D. program via

Ms. Kitzen. (The funding ultimately came from the RMP grant mentioned in M-2). Secondly, some anxiety was expressed that this money was actually going to come out of RMP money allocated to the E.S.R.D. program per se, in spite of repeated assurances to the contrary. This confusion cleared up but the concern over competition for subsequent funding was not and I was subsequently informed in confidence that this was perceived as a real, not hypothetical, potential problem, ergo the authorship of this statement will remain unrevealed.

Consequently, the two aforementioned factors both summated to necessitate changing the sample size while the study was in progress. Ultimately, the study consisted of a forty percent alphabetic, random sample of only the center based dialysis patients at the Yale New Haven Unit (16 patients), St. Mary's Hospital Unit (8), St. Rapheal's Hospital Unit (7), and Danbury Hospital Unit (8 patients), as well as a 100% sample of the V.A. (W.H.) center based dialysis unit (12 patients).

The sampel size was consequently 50 patients, about 10 percent of the Connecticut dialysis population. The entire V.A. CBD population was included because unlike the other facilities a minority (less than 1/4) of its total patient population on CBD dialysis according to Dr. Ernest Hendler. I consequently felt that a forty percent sample of this population would not even give a theoretically credible representation of the V.A. population.

The Instrument

Although there is no aggregate data concerning the documented nature of the Connecticut E.S.R.D. experience, there is plenty available pertaining to the nature of problems likely to be encountered by any E.S.R.D. patient. Much of this information is dealt with in the California R.M.P. Criteria and Standards final report and this document was referred to often in the design of my instrument. This was not the predominant information source utilized. In order to assure that the instrument would attempt to address the Connecticut experience as perceived by the State's resident professionals, ideas and insight were derived from the letters, memoranda and guidelines presented to the networks Quality of Care Subcommittee. The latter suggestions correspond well with those of the California group.

Information was available from (1) the now Chairman of the M.R.B. (M-5), (2) the now E.S.R.D. Program Executive Director (M-6), (3) the dialysis dieticians (M-7), (4) an eminent concerned nephrologist in the State (M-9), (5) various Yale protocols (M-10, M-11), and (6) the Networks response to the California R.M.P. project mentioned above (M-12).

The salient parts of these materials were summated and the instrument (M-1) was evolved with aide-consultation with Doctors Finkelstein and Doolan.

All of the charts were abstracted by the author, a fifth year M.D./M.P.H. (Hospital Administration) candidate, onto the code sheet, key punched and subsequently analyzed using a Data text canned program on an IBM-360 Series computer. Frequencies, crosstabulations and correlations were done as deemed appropriate and are presented in the following results and discussion section.

Problems With Methodology

The instrument presented little problems in data abstraction and coding except in the area of renal transplantation where the operation was often alluded to in the charts, i.e., patient wonders about getting a kidney but with so little if any evidence of professional notes or discussion of the alternative with the patient that I felt I would be just guessing how much information the patient actually received. Successful transplant patients, who were at least ostensibly well informed, would not be included in my patient population and consequently the data obtained would be negatively biased. It was unfortunately therefore decided to omit the transplant variables from the results presentation.

Three other points need clarification before proceeding to the results and discussion: (1) "Not available" was utilized whenever an isolated part of a chart for a given period or item was missing and consequently no conclusive statement about the

item was codable, "Blank" means that either a significant part of the chart was missing or irretrievable or the item was simply not referred to in the chart; (2) a literal scale for assessment of the Strength of Association and Chi-squares as follows was utilized: 0-.20 weak or poor, .20-.30 weakly moderate, .40-.60 moderate, .60-.70 moderately strong, .70-.90 strong, .90 very strong, and (3) difficulty arose attempting to differentiate M.D.'s in training from "true" nephrologist and they were consequently counted with the "trues" for statistical purposes.

length on dialysis (30 months) and mean length (38.2) of patients in the E.S.R.D. program suggest that many patients had their E.S.R.D. identified and were included in the program after passage of the 1972 law and during the period when the interim regulations were in effect. The impact of the older and high risk patients included during this time period and the age distribution of the population at risk also may be contributing to the increase in age for the dialysis population sampled.

It should be noted that there was no significant differentiation noted between the age of patient by sex. (Correlation #1).

Intake Parameters

A) Documentation of Chronic Renal Failure or E.S.R.D.

Seventy-eight percent of the charts documented that the patient had chronic renal failure and/or E.S.R.D. Initial serum creatinines greater than 10mg/100ml and creatinine clearances less than 5 ml/min were given as starting points for dialysis in 63% and 16% of the sample population, respectively. The remaining 21% of the population had no documented corroborative laboratory evidence of E.S.R.D. or chronic renal failure on intake. The major collabrative evidence given along with serum or clearance values in order of decreasing priority were: unsatisfactory control of chronic heart failure,

nausea and vomiting, unsatisfactory control of hypertension, cerebral dysfunction and intractible fatigue and weakness. It should also be noted that 13% of the sample population not included in the priority ranking above had two or more collaborative factors listed.

B) Psychosocial Parameters and Initial Evaluation

There is a weakly moderate, highly significant association between whether a person is informed of his treatment options and whether he is informed of realistic expectations of his eventual response to various types of treatment. Informing a patient of the options and the patients' and families' acceptance of treatment were similarly associated. (See Crosstabs 2, 3).

The highly significant, moderately strong association and corresponding strong strength of the association between a patient's being realistically informed about expectations and his and the family's acceptance of treatment underscore the positive benefits of a patient's invovlement in and understanding of his illness and his coping ability. (See Crosstab 4) "Patient informing value" was considered very important by the California RMP group who recommend a 100% compliance with this variable. Connecticut's 76% value illustrates its appreciation of this variable albeit its documentation falls short of the aforementioned criteria.

The variable also appears to influence from a moderate to weakly moderate extent the initial documentation and perhaps the

nausea and vomiting, unsatisfactory control of hypertension, cerebral dysfunction and intractible fatigue and weakness. It should also be noted that 13% of the sample population not included in the priority ranking above had two or more collaborative factors listed.

B) Psychosocial Parameters and Initial Evaluation

There is a weakly moderate, highly significant association between whether a person is informed of his treatment options and whether he is informed of realistic expectations of his eventual response to various types of treatment. Informing a patient of the options and the patients' and families' acceptance of treatment were similarly associated. (See Crosstabs 2, 3).

The highly significant, moderately strong association and corresponding strong strength of the association between a patient's being realistically informed about expectations and his and the family's acceptance of treatment underscore the positive benefits of a patient's invovlement in and understanding of his illness and his coping ability. (See Crosstab 4) "Patient informing value" was considered very important by the California RMP group who recommend a 100% compliance with this variable. Connecticut's 76% value illustrates its appreciation of this variable albeit its documentation falls short of the aforementioned criteria.

The variable also appears to influence from a moderate to weakly moderate extent the initial documentation and perhaps the

behaviour of other health care professionals involved in the management of E.S.R.D. patients. The association between the patient informing variable was greatest for the initial psych evaluation followed by initial social workers evaluation, initial nursing and initial dietary evaluations with the corresponding decreases in the strength of associations as listed. (See Crosstabs 5-8).

The moderate and weakly moderate decreasing associations are influenced by the relatively low documentation of such evaluations in the predialysis evaluations for the health professionals alluded to above (14% psych, 54% S.W., 66% nursing and 60% dietary) and point to the autonomy of these professionals and underscores the potential benefit of greater team work.

No significant association was found between whether a patient was informed of the options by a physician and (1) the length of a patient in the E.S.R.D. program or (2) the reason for exclusion from home dialysis. The predominate reasons for such exclusion being (1) no partner, (2) medically unsuitable. For 26% of the patients no evidence of the possibility of home dialysis was found in his charts. There is only a weak, highly significant association between whether a patient had been informed of a home dialysis option and whether a patient was scheduled for or being trained for home dialysis.

No significant association between whether a patient was informed of realistic expectations and the reason for exclusion from home dialysis was found either. (Crosstab 9).

There is only a weak association with moderate strengths of association between the patients initial professional non-MD workups and whether a patient was informed of realistic expectations. Consequently, a pivotal role appears attributable to the M.D. as coordinator of the patient's care and patient educator. The federal legislation mandated a patient care coordinator and stipulates that this person is to be appointed by the physician director of a given facility. The above data raise the question who if anyone has been designated the role with respect to the initial workup of the sample population. The association between workups and realistic expectations in increasing order of workups are social work, psychiatry, nursing and dietary. (See Crosstabs 10, 11, 12, 13).

There is also only a weak association with moderate strength of association, albeit highly significant, between the initial workup documentation and the patients' and families' acceptance of treatment. They are dietary, social work, nursing, and psychiatric in increasing strengths of association. The highly significant, strong association between acceptance of treatment and the patients being informed of the options by a doctor corroborates the previous evidence for the pivotal role of the M.D. as manager. (Crosstabs 14, 15, 16, 17). The percentage of initial evaluation listed demonstrate the extent to which this challenge appears to be met.

The constantly changing relative order of the associations for the initial workup parameters and the patients psychosocial adjustments and expectations raises the question as to what roles do the

patient and his doctor assign the other health professionals in a patient's management. The importance of this question becomes clearer when one considers that all of the units visited utilized a variation of primary care nursing and many had social workers in residence allegedly making daily rounds. Nursing documentation, unlike the other allied health professionals', showed absolute percentage consistency (albeit the Chi-squares varied) in its influence on the patients psychosocial and intake parameters. (See Crosstabs 7, 13, 17, 19).

There are moderate associations with moderate strong strengths of association between initial psych and initial social worker workup documentation as well as between initial psych and initial nursing evaluation documentation. There is moderately weak association between initial nursing evaluation and initial dietary evaluation with a corresponding strength of association as well as a weak association and strength of association for psych and diet. These findings are not surprising when one takes into consideration the initial workup percentages. These suggest that the quality of the initial workup documentation is likely to be good or poor for all the parameters. (See Crosstabs 18-21).

There is poor documentation of whether a patient is medically or psychologically suitable for transplantation, 72% and 84% of patients with no notes, respectively. There is, however, a highly significant, moderately strong association between these two variables with strong strengths of association as might be expected from optimal medical practices. The above percentages

suggest that this should be an area for further investigation and effort. (Crosstab 22).

Continued Professional Documentation

There is a very weak, negative correlation between the last comprehensive nursing evaluation documentation and the initial nursing evaluation. There is a better but still weak correlation between the last documented comprehensive dietary evaluation and the initial dietary evaluation. In fact the R^2 for these correlations clearly shows the insubstantial influence of these correlated factors on one another. (See Correlation 2 & 6). There is a 6% gain in the number of patients without recent documented dietary workups from the 14% without initial dietary evaluation documentation.

There is a moderate association with a strong strength of association between the initial dietary documentation and chart evidence documenting a Na, K, fluid and protein order and a similar association and strength between the former variable and whether there was a note by a registered dietician within the last fiscal year (1977). This implies some consistency in dietary management for those patients receiving dietary services. Unfortunately only 30% of the patients had had a dietary consult documented in the last 3 months before this study. Another 30%

had no dietary doucmentation noted for the last fiscal year. (Crosstabs 23, 24). These values fall far short of the Connecticut dialysis dieticians' suggested recommendations for follow-up evaluation every 3 months.[50]

The above data raise the question of the consistency of nursing and dietary services and imply that they may be either sporadic across the sample group or that there are inconsistent services for a considerable portion of the group.

Unfortunately, correlations between the initial social worker evaluation documentation rate and the last comprehensive social worker evaluation were not obtained. There is no significant correlation between the last documented comprehensive social worker evaluation and the frequency of social worker consultation documented over the last fiscal year. (See Correlation #3).

The following facts (1) initial social worker evaluation documentation rate of 54% and (2) only 18% social worker consults in last month, (3) 34% documentation within last 2 months, (4) 72% documentation within last 1/3 year and (5) 50% of the patients had no social worker or less than 3 social worker consults documented in fiscal year 1976-77, do not compare favorably with the weekly contact recommended by the Committee of Nephrology Social Workers of Connecticut in its suggested guidelines.[51]

Correlations between whether a patient was informed of his options by a physician and (1) the frequency of documentated nephrology consults in the aforementioned fiscal year or (2) the last documented nephrology consult were also not obtained.

An average of 63% of the patients were documented as seen by a physician more frequently than once a month, 75% at least every two months with a median and mean of frequency of documented contact of 1 month. Consistent with these figures 65% of the patients were seen in the month before this study and 85% in the last 2 months. There is a weakly moderate negative correlation (significant at the .05 level), between the frequency of documented nephrology contact and the patient's documented nephrology consult, paradoxically suggesting that the more frequently the patient was seen the less likely he was to be seen recently. (Correlation #4).

Dialysis Evaluation Parameters

Seventy-two percent of the patients were dialyzed three times a week, twelve percent were dialyzed four times a week. There is a median of 3.0/wks and a mean of 3.5/week. Consistent with generally accepted treatment regimens for stable dialysis patients.

Only 15.5% of the population had no documentation of transfusion. The significance of this figure is weakened by the 25% blank or unavailable response rate indicating missing chart

(lab values) or irretrieveable charts for the period in question (fiscal 1976-77). The largest subgroup of the population 28% had been transfused only once; however there was a mean of 4.47 transfusions and a median of 2.0 indicating that the distribution is showed by the multiple transfusions for a small number of patients. It was not always possible to differentiate whether a patient's transfusions were for E.S.R.D. related anemia or concomitant patient problems (i.e., surgery with "prophylactic transfusion") which would give the erroneous impression that more people were transfused or that some were transfused more frequently than necessary to control their E.S.R.D. related anemia.

The patients Hct and/or Hbg was documented as drawn about every five weeks with a mean of 4.8, median 5.0 and S.D.2. 173. The greatest subgroup 38% had the Hct taken every 5 weeks, followed by 20% every 2 weeks and 16% every 3 weeks accounting for 72% within every 5 week period. There is no "standard" frequency of Hct or Hgb for dialysis patients. The Yale protocol recommends monthly blood indicies. The California RMP group similarly recommends 100% compliance with monthly Hct or Hgb testing. Sixteen of the patients had no reliable information on Hct/Hgb testing available for the study period.

The CBC documented drawing frequency had an essentially bimodal distribution with 22% and 38% of the patients having

documented test at 2 and 4 week intervals, respectively. A mean of 5.3 and a median of 4.0 demonstrate the influence of the 16% unavailable.

No crosstabs between CBC, Hct and the times the patients were transfused were done. There is a highly significant, strong association between the frequency of CBC documentation and the frequency of platelet documentation (See Crosstab 43). There is also a highly significant, strong association with moderate strength of association between thefrequency of CBC documentation and the documented frequency rate for electrolyte drawing.

There is a similar association between the latter variable and the frequency rate of K documentation as well as between it and the frequency rate of BUN and creatinine documentation. The respective frequencies are presented along with the crosstabs (see Crosstabs 26, 27, 28).

The strong association between CBC and platelets, CBC and electrolytes, as well as electrolytes and BUN are anticipatable where the patient population is essentially a stable one (sporadic problems with patient compliance and/or simultaneous illness causing the majority of "acute" problems) and these tests are consequently drawn as routine test for long term monitoring. The percent of information unavailable for these tests (about 16-18%) is the same which is highlighted by the strength of their association and underscores their pattern of documentary consistency.

The strong association between Potassium (K^+) sample documentation and routine electrolyte documentation is also logically anticipatable whereas most clinical situations in which the dialysis physician would be concerned about the other electrolytes, he would be concerned about the K^+ also (e.g., fluid balance, electrolyte wasting, activity of non-resected kidney) and consequently they all would be drawn simultaneously and correspondingly documented.

The eight percent of patients with greater than 5% fluctuation in body weight and the 71% without this degree of fluctuation attest to the role of patient compliance in controlling the need for fluid balancing and electrolytes sampling. The 21% unaccounted for subgroup, slightly higher than the aforementioned lab test values, prevent any unequivocal statement being made concerning the "true" magnitude of this impact for any but the documented 79%.

There is an alarming 20% in evidence in the sample of documented peri-dialysis symptomatic hypotension which may reflect over zealous attempts to remove fluid excess due to poor patient compliance, difficulty with dialysates, difficulty getting patients off the pump, vasovagal episodes and psychosocial manipulation attendant to otherwise non-symptomatic hypotension to mention a few. The former if existent is unable to be assessed from this data because the problem patients may well be hidden in the unavailable category of the 5% fluid fluctuation frequency distribution. It should

be noted that symptomatic was applied in its most literal sense when I abstracted these charts. The majority of the complaints were of nausea and/or dizziness. I did not encounter any emergent episodes (e.g., abdominal insufficiency, loss of consciousness, coronary insufficiency, shock) in the population.

Another area where dialysis patients have routine potential for problems is in the regulation of calcium phosphate (Ca^{++}, $PO_4^=$) levels. The percent distribution for documentation of these test closely parallels the aforementioned routine assessment parameters. I do not have any cross-tabulations between them and any of the previous variables to determine the strength of association or its significance level but the consistency is logically anticipatable.

There is a highly significant, moderate strenghtened association between the frequency of Alkaline Phosphatose (AP) documentation and the frequency of Ca^{++} and $PO_4^=$ documentation. There is also a highly significant, moderately strong strengthened association between AP documentation and the frequency of transaminase documentation (SGOT and SGPT) (See Crosstabs 29, 30). These crosstabs suggest a possible dual role for AP in the management of patients with E.S.R.D. (1) as a screen for Ca, $PO_4^=$ metabolic problems consequent to renal osteodystrophy and (2) as a screen for hepatitis or hepatitic related sequelae.

The duality is further underscored by the highly significant, moderately strong strength of associations between both

the frequency of AP and the frequency of SGOT/PT documentation with the frequency of Australia Antigen (AA) drawing documentation (See Crosstabs 31, 32).

I did not differentiate between isoenzymes for AP when abstracting the patients charts largely because I did not "recall" seeing values fractionated as such.

Consequent to its dual role, it is difficult to interpret unequivocally the 8% of the population with a documented 50% rise in AP during fiscal 1976-77. The low incidence of hepatitis (about 2%) makes the role of this complication appear minimal when compared to the 12% of patients who have bone fractures. The 10% incidence difference notwithstanding, the picture is clouded by the hypothetical ambiguity in differentiating between those patients with bone fractures consequent to renal osteodystrophy per se and those patients, possibly elderly, with trauma, borderline Ca, $PO_4^=$ problems and bone fractures. None of the patients with bone fractures had a 50% rise in AP, ergo the role of osteodystrophy appears to be minimal, at least as judged by this 50% threshold value (Crosstab 33).

Other routine lab test for long term management of E.S.R.D. patients include serum iron (Fe), iron binding capacity (Fe BC) and serum glucose (G).

CROSSTABS

58

```
                          NEGRO    LA SUR   AA SUR   N AMER   CAUCAS
                                   NAME     NAME     ICAN     IAN
                          1        2        3        4        5        TOTAL
                        I--------I--------I--------I--------I--------I
                        I 50.0%  I        I        I        I 55.0%  I
          MALE          I        I        I        I        I        I  52.0%
            1           I        I        I        I        I        I    26
VAR(65)                 I      4 I        I        I        I     22 I
SEX                     I--------I--------I--------I--------I--------I
                        I 50.0%  I100.0%  I        I        I 45.0%  I
          FEMALE        I        I        I        I        I        I  48.0%
            2           I        I        I        I        I        I    24
                        I      4 I      2 I        I        I     18 I
                        I--------I--------I--------I--------I--------I
                PERCENT   16.0%     4.0%     0.0%     0.0%    80.0%   100.0%
                TOTAL        8        2        0        0       40       50
UPPER CELL ENTRIES ARE PER CENT OF COLUMN TOTALS

CHI-SQUARE                                2.324         SIGNIFICANT AT .313 WITH 2 DEGREES
CRAMER'S V                                0.216

TABLE SUMMARY

TOTAL NUMBER OF UNITS IN TABLE                          50
```

①

```
                                                     CORRELATION COEFFICIENTS   (8)

                                                    VAR- Age
     VARIABLE DESCRIPTION       NAME                (2)
     FREQ NEPHRO CONSULT        VAR(62)            0.022

     ALL CORRELATIONS BASED ON     43 UNITS.        7 BLANK UNITS OMITTED.
```

②

```
                                   VAR(10)
                                   PT INFORMED REAL EXPECTS

                         YES         NO         UNAVAI
                                                L
                          1           2         3           TOTAL
                        I---------I---------I---------I
                        I 84.1%   I 33.3%   I         I
        YES             I         I         I         I
            1           I         I         I         I     76.0%
                        I      37 I       1 I         I      38
                        I---------I---------I---------I
                        I  9.1%   I 66.7%   I         I
        NO              I         I         I         I
             2          I         I         I         I
VAR(9)                  I       4 I       2 I         I     12.0%
PT INFORMED OPTS BY DOC I---------I---------I---------I      6
                        I  6.8%   I         I100.0%   I
        UNAVAIL         I         I         I         I
            3           I         I         I         I     12.0%
                        I       3 I         I       3 I      6
                        I---------I---------I---------I

              PERCENT     88.0%       6.0%      6.0%       100.0%
              TOTAL        44          3         3           50

UPPER CELL ENTRIES ARE PERCENT OF COLUMN TOTALS

CHI-SQUARE                                  32.224***      SIGNIFICANCE UNDER .001
CRAMER'S V                                   0.568

TABLE SUMMARY

TOTAL NUMBER OF UNITS IN TABLE                                50
```

③

```
                                   VAR(11)
                                   PT AND FAM ACCEPT RX

                         YES         NO         UNAVAI
                                                L
                          1           2         3           TOTAL
                        I---------I---------I---------I
                        I 84.1%   I         I 25.0%   I
        YES             I         I         I         I
            1           I         I         I         I     76.0%
                        I      37 I         I       1 I      38
                        I---------I---------I---------I
                        I  9.1%   I100.0%   I         I
        NO              I         I         I         I
             2          I         I         I         I
VAR(9)                  I       4 I       2 I         I     12.0%
PT INFORMED OPTS BY DOC I---------I---------I---------I      6
                        I  6.8%   I         I 75.0%   I
        UNAVAIL         I         I         I         I
            3           I         I         I         I     12.0%
                        I       3 I         I       3 I      6
                        I---------I---------I---------I

              PERCENT     88.0%       4.0%      8.0%       100.0%
              TOTAL        44          2         4           50

UPPER CELL ENTRIES ARE PERCENT OF COLUMN TOTALS

CHI-SQUARE                                  31.419***      SIGNIFICANCE UNDER .001
CRAMER'S V                                   0.561

TABLE SUMMARY

TOTAL NUMBER OF UNITS IN TABLE                                50
```

④

```
                                         VAR(11)
                                         PT AND FAM ACCEPT RX

                                   YES       NO        UNAVAI
                                                       L
                                   1         2         3         TOTAL
                                I--------I--------I--------I
                                I 97.7%  I        I 25.0%  I
               YES              I        I        I        I
                  1             I        I        I        I   88.0%
                                I     43 I        I      1 I    44
                                I--------I--------I--------I
                                I  2.3%  I100.0%  I        I
               NO               I        I        I        I
                  2             I        I        I        I    6.0%
VAR(10)                         I      1 I      2 I        I     3
PT INFORMED REAL EXPECTSI--------I--------I--------I
                                I        I        I 75.0%  I
               UNAVAIL          I        I        I        I
                  3             I        I        I        I    6.0%
                                I        I        I      3 I     3
                                I--------I--------I--------I

                   PERCENT        38.0%     4.0%     8.0%   100.0%
                   TOTAL           44        2        4      50

UPPER CELL ENTRIES ARE PERCENT OF COLUMN TOTALS

CHI-SQUARE                                        69.249***      SIGNIFICANCE UNDER .00
CRAMER'S V                                         0.832

TABLE SUMMARY

TOTAL NUMBER OF UNITS IN TABLE                                   50
```

```
                                          VAR(12)
                                          INIT PSYCH EVALUATION
                                 YES       NO        UNAVAI
                                                     L
                                 1         2         3         TOTAL
                              I--------I--------I--------I
                              I 57.1%  I 91.4%  I 25.0%  I
             YES              I        I        I        I
               1              I        I        I        I    76.0%
                              I      4 I     32 I      2 I     38
                              I--------I--------I--------I
                              I 42.9%  I  8.6%  I        I
             NO               I        I        I        I
               2              I        I        I        I    12.0%
 VAR(9)                       I      3 I      3 I        I      6
 PT INFORMED OPTS BY DOC      I--------I--------I--------I
                              I        I        I 75.0%  I
             UNAVAIL          I        I        I        I
               3              I        I        I        I    12.0%
                              I        I        I      6 I      6
                              I--------I--------I--------I

                     PERCENT    14.0%     70.0%     16.0%     100.0%
                     TOTAL        7        35         8         50

 UPPER CELL ENTRIES ARE PERCENT OF COLUMN TOTALS

 CHI-SQUARE                                        42.519***      SIGNIFICANCE UNDER .001
 CRAMER'S V                                         0.652

 TABLE SUMMARY

 TOTAL NUMBER OF UNITS IN TABLE                                  50
```

(5)

```
                                          VAR(13)
                                          INITIAL S W EVALUATION
                                 YES       NO        UNAVAI
                                                     L
                                 1         2         3         TOTAL
                              I--------I--------I--------I
                              I 88.9%  I 78.6%  I 33.3%  I
             YES              I        I        I        I
               1              I        I        I        I    76.0%
                              I     24 I     11 I      3 I     38
                              I--------I--------I--------I
                              I 11.1%  I 21.4%  I        I
             NO               I        I        I        I
               2              I        I        I        I    12.0%
 VAR(9)                       I      3 I      3 I        I      6
 PT INFORMED OPTS BY DOC      I--------I--------I--------I
                              I        I        I 66.7%  I
             UNAVAIL          I        I        I        I
               3              I        I        I        I    12.0%
                              I        I        I      6 I      6
                              I--------I--------I--------I

                     PERCENT    54.0%     28.0%     18.0%     100.0%
                     TOTAL       27        14         9         50

 UPPER CELL ENTRIES ARE PERCENT OF COLUMN TOTALS

 CHI-SQUARE                                        32.226***      SIGNIFICANCE UNDER .001
 CRAMER'S V                                         0.568

 TABLE SUMMARY

 TOTAL NUMBER OF UNITS IN TABLE                                  50
```

(6)

```
                                   VAR(14)
                                   INIT PREDIAL NURS EVAL

                         YES      NO       UNAVAI
                                           L
                         1        2        3        TOTAL
                      I--------I--------I--------I
                      I 84.8%  I 87.5%  I 33.3%  I
          YES         I        I        I        I
             1        I        I        I        I   76.0%
                      I     28 I      7 I      3 I    38
                      I--------I--------I--------I
                      I 15.2%  I 12.5%  I        I
          NO          I        I        I        I
             2        I        I        I        I   12.0%
VAR(9)                I      5 I      1 I        I     6
PT INFORMED OPTS BY DOC I--------I--------I--------I
                      I        I        I 66.7%  I
          UNAVAIL     I        I        I        I
             3        I        I        I        I   12.0%
                      I        I        I      6 I     6
                      I--------I--------I--------I

               PERCENT   66.0%    16.0%    18.0%   100.0%
               TOTAL      33        8        9       50

UPPER CELL ENTRIES ARE PERCENT OF COLUMN TOTALS

CHI-SQUARE                              31.323***      SIGNIFICANCE UNDER .001
CRAMER'S V                               0.560

TABLE SUMMARY

TOTAL NUMBER OF UNITS IN TABLE                           50
```

⑦

```
                                   VAR(16)
                                   INIT EVAL DIETICIAN

                         YES      NO       UNAVAI
                                           L
                         1        2        3        TOTAL
                      I--------I--------I--------I
                      I 84.8%  I 71.4%  I 37.5%  I
          YES         I        I        I        I
             1        I        I        I        I   75.0%
                      I     28 I      5 I      3 I    36
                      I--------I--------I--------I
                      I 12.1%  I 28.6%  I        I
          NO          I        I        I        I
             2        I        I        I        I   12.5%
VAR(9)                I      4 I      2 I        I     6
PT INFORMED OPTS BY DOC I--------I--------I--------I
                      I  3.0%  I        I 62.5%  I
          UNAVAIL     I        I        I        I
             3        I        I        I        I   12.5%
                      I      1 I        I      5 I     6
                      I--------I--------I--------I

               PERCENT   68.8%    14.6%    16.7%   100.0%
               TOTAL      33        7        8       48

UPPER CELL ENTRIES ARE PERCENT OF COLUMN TOTALS

CHI-SQUARE                              23.631***      SIGNIFICANCE UNDER .001
CRAMER'S V                               0.496

TABLE SUMMARY

TOTAL NUMBER OF UNITS IN TABLE                           48
NUMBER OF UNITS OMITTED DUE TO WILD SCORES               2
```

⑧

64

```
                                                   [illegible] CYCLE REASON
                      NO PRT    SPACE     NO UNS    LIV RE    DOC DT    SEVARO    UNAVAI
                      NER       FACIL     TABLE     L DON     SAPP      V         L
                      1         2         3         4         5         6         7          TOTAL
                     I--------I--------I--------I--------I--------I--------I--------I
                     I100.0%  I100.0%  I 85.7%  I100.0%  I        I        I 84.6%  I
          YES        I        I        I        I        I        I        I        I
            1        I        I        I        I        I        I        I        I   90.7%
                     I     14 I      1 I     12 I      1 I        I        I     11 I     39
                     I--------I--------I--------I--------I--------I--------I--------I
                     I        I        I  7.1%  I        I        I        I        I
          NO         I        I        I        I        I        I        I        I
            2        I        I        I        I        I        I        I        I    2.3%
VAR(10)              I        I        I      1 I        I        I        I        I      1
PT INFORMED REAL EXPECTSI--------I--------I--------I--------I--------I--------I--------I
                     I        I        I  7.1%  I        I        I        I 15.4%  I
          UNAVAIL    I        I        I        I        I        I        I        I
            3        I        I        I        I        I        I        I        I    7.0%
                     I        I        I      1 I        I        I        I      2 I      3
                     I--------I--------I--------I--------I--------I--------I--------I
              PERCENT   32.6%     2.3%    32.6%     2.3%     0.0%     0.0%    30.2%    100.0%
              TOTAL      14        1       14        1        0        0       13        43
UPPER CELL ENTRIES ARE PERCENT OF COLUMN TOTALS

CHI-SQUARE                           4.749        SIGNIFICANCE OVER .5 WITH 8 DEGREES OF FREEDOM
CRAMER'S V                           0.235

TABLE SUMMARY

TOTAL NUMBER OF UNITS IN TABLE                  43
NUMBER OF UNITS OMITTED DUE TO BLANKS            7
```

⑨

```
                                        VAR(12)
                                        INIT PSYCH EVALUATION
                                  YES         NO          UNAVAI
                                                          L
                                  1           2           3          TOTAL
                              I---------I-----------I-----------I
                              I  85.7%  I   94.3%   I   62.5%   I
                 YES          I         I           I           I
                    1         I         I           I           I
                              I       6 I        33 I         5 I    88.0%
                              I---------I-----------I-----------I     44
                              I  14.3%  I    5.7%   I           I
                 NO           I         I           I           I
                    2         I         I           I           I
VAR(10)                       I         I           I           I     6.0%
PT INFORMED REAL EXPECTS      I       1 I         2 I           I      3
                              I---------I-----------I-----------I
                 UNAVAIL      I         I           I   37.5%   I
                    3         I         I           I           I
                              I         I           I           I     6.0%
                              I         I           I         3 I      3
                              I---------I-----------I-----------I
                  PERCENT      14.0%        70.0%       16.0%       100.0%
                  TOTAL         7           35          8            50
UPPER CELL ENTRIES ARE PERCENT OF COLUMN TOTALS

CHI-SQUARE                                        17.788**         SIGNIFICANT AT .002
CRAMER'S V                                         0.422

TABLE SUMMARY

TOTAL NUMBER OF UNITS IN TABLE
                                                               50
```

⑩

```
                                        VAR(13)
                                        INITIAL S W EVALUATION
                                  YES         NO          UNAVAI
                                                          L
                                  1           2           3          TOTAL
                              I---------I-----------I-----------I
                              I  92.6%  I   92.9%   I   66.7%   I
                 YES          I         I           I           I
                    1         I         I           I           I
                              I      25 I        13 I         6 I    88.0%
                              I---------I-----------I-----------I     44
                              I   7.4%  I    7.1%   I           I
                 NO           I         I           I           I
                    2         I         I           I           I
VAR(10)                       I         I           I           I     6.0%
PT INFORMED REAL EXPECTS      I       2 I         1 I           I      3
                              I---------I-----------I-----------I
                 UNAVAIL      I         I           I   33.3%   I
                    3         I         I           I           I
                              I         I           I           I     6.0%
                              I         I           I         3 I      3
                              I---------I-----------I-----------I
                  PERCENT      54.0%        28.0%       18.0%       100.0%
                  TOTAL         27          14          9            50
UPPER CELL ENTRIES ARE PERCENT OF COLUMN TOTALS

CHI-SQUARE                                        14.894**         SIGNIFICANT AT .006
CRAMER'S V                                         0.386

TABLE SUMMARY

TOTAL NUMBER OF UNITS IN TABLE
                                                               50
```

⑪

```
                                        VAR(16)
                                        INIT EVAL DIETICIAN
                               YES      NO        UNAVAI
                                                  L
                               1        2         3         TOTAL
                             I--------I--------I--------I
              YES            I 97.0%  I 57.1%  I 75.0%  I
                 1           I        I        I        I
                             I     32 I      4 I      6 I   87.5%
                             I--------I--------I--------I    42
              NO             I        I 42.9%  I        I
                 2           I        I        I        I
VAR(10)                      I        I        I        I    6.3%
PT INFORMED REAL EXPECTS     I        I      3 I        I     3
                             I--------I--------I--------I
              UNAVAIL        I  3.0%  I        I 25.0%  I
                 3           I        I        I        I
                             I      1 I        I      2 I    6.3%
                             I--------I--------I--------I     3
                   PERCENT     68.8%    14.6%    16.7%    100.0%
                   TOTAL        33        7        8        48
UPPER CELL ENTRIES ARE PERCENT OF COLUMN TOTALS

CHI-SQUARE
CRAMER'S V                                        24.275***       SIGNIFICANCE UNDER .001
                                                   0.503
```

⑫

```
                                        VAR(14)
                                        INIT PREDIAL NURS EVAL
                               YES      NO        UNAVAI
                                                  L
                               1        2         3         TOTAL
                             I--------I--------I--------I
              YES            I 97.0%  I 75.0%  I 66.7%  I
                 1           I        I        I        I
                             I     32 I      6 I      6 I   88.0%
                             I--------I--------I--------I    44
              NO             I  3.0%  I 25.0%  I        I
                 2           I        I        I        I
VAR(10)                      I        I        I        I    6.0%
PT INFORMED REAL EXPECTS     I      1 I      2 I        I     3
                             I--------I--------I--------I
              UNAVAIL        I        I        I 33.3%  I
                 3           I        I        I        I
                             I        I        I      3 I    6.0%
                             I--------I--------I--------I     3
                   PERCENT     66.0%    16.0%    18.0%    100.0%
                   TOTAL        33        8        9        50
UPPER CELL ENTRIES ARE PERCENT OF COLUMN TOTALS

CHI-SQUARE
CRAMER'S V                                        20.426***       SIGNIFICANCE UNDER .001
                                                   0.452

TABLE SUMMARY

TOTAL NUMBER OF UNITS IN TABLE                           50
```

⑬

```
                                        VAR(13)
                                        INITIAL  S W EVALUATION
                                 YES         NO         UNAVAI
                                                        L
                                  1           2         3         TOTAL
                               I--------I--------I--------I
                               I  92.6% I100.0%  I  55.6% I
                 YES           I        I        I        I
                    1          I        I        I        I       88.0%
                               I     25 I     14 I      5 I        44
                               I--------I--------I--------I
                 NO            I   7.4% I        I        I
                    2          I        I        I        I
          VAR(11)              I        I        I        I        4.0%
          PT  AND  FAM ACCEPT RX      2 I        I        I         2
                               I--------I--------I--------I
                 UNAVAIL       I        I        I  44.4% I
                    3          I        I        I        I
                               I        I        I        I        8.0%
                               I        I        I      4 I         4
                               I--------I--------I--------I
                       PERCENT    54.0%     28.0%     18.0%     100.0%
                       TOTAL       27        14         9         50
          UPPER CELL ENTRIES ARE PERCENT OF COLUMN TOTALS

          CHI-SQUARE                                     21.296***      SIGNIFICANCE UNDER .001
          CRAMER'S V                                      0.461

          TABLE SUMMARY

          TOTAL NUMBER OF UNITS IN TABLE                              50
```

⑭

```
                                        VAR(16)
                                        INIT EVAL DIETICIAN
                                 YES         NO         UNAVAI
                                                        L
                                  1           2         3         TOTAL
                               I--------I--------I--------I
                               I  93.9% I  71.4% I  75.0% I
                 YES           I        I        I        I
                    1          I        I        I        I       87.5%
                               I     31 I      5 I      6 I        42
                               I--------I--------I--------I
                 NO            I        I  28.6% I        I
                    2          I        I        I        I
          VAR(11)              I        I        I        I        4.2%
          PT  AND  FAM ACCEPT RX        I      2 I        I         2
                               I--------I--------I--------I
                 UNAVAIL       I   6.1% I        I  25.0% I
                    3          I        I   /    I        I
                               I        I        I        I        8.3%
                               I      2 I        I      2 I         4
                               I--------I--------I--------I
                       PERCENT    68.8%     14.6%     16.7%     100.0%
                       TOTAL       33         7         8         48
          UPPER CELL ENTRIES ARE PERCENT OF COLUMN TOTALS

          CHI-SQUARE                                     15.675**      SIGNIFICANT AT .004
          CRAMER'S V                                      0.404

          TABLE SUMMARY

          TOTAL NUMBER OF UNITS IN TABLE                              48
          NUMBER OF UNITS OMITTED DUE TO WILD SCORES                   2
```

⑮

```
                                   VAR(11)
                                   PT AND FAM ACCEPT RX

                            YES       NO       UNAVAI
                                               L
                             1         2       3           TOTAL
                          I--------I--------I--------I
                          I 13.6%  I 50.0%  I        I
           YES            I        I        I        I
              1           I        I        I        I     14.0%
                          I      6 I      1 I        I        7
                          I--------I--------I--------I
                          I 77.3%  I 50.0%  I        I
           NO             I        I        I        I
              2           I        I        I        I     70.0%
VAR(12)                   I     34 I      1 I        I       35
INIT PSYCH EVALUATION     I--------I--------I--------I
                          I  9.1%  I        I100.0%  I
           UNAVAIL        I        I        I        I
              3           I        I        I        I     16.0%
                          I      4 I        I      4 I        8
                          I--------I--------I--------I

                  PERCENT    88.0%     4.0%     8.0%    100.0%
                  TOTAL       44        2        4        50

UPPER CELL ENTRIES ARE PERCENT OF COLUMN TOTALS

CHI-SQUARE                                 24.935***     SIGNIFICANCE UNDER .001
CRAMER'S V                                  0.499

TABLE SUMMARY

TOTAL NUMBER OF UNITS IN TABLE                               50
```

⑯

```
                                   VAR(14)
                                   INIT PREDIAL NURS EVAL

                            YES       NO       UNAVAI
                                               L
                             1         2       3           TOTAL
                          I--------I--------I--------I
                          I 97.0%  I 87.5%  I 55.6%  I
           YES            I        I        I        I
              1           I        I        I        I     88.0%
                          I     32 I      7 I      5 I       44
                          I--------I--------I--------I
                          I  3.0%  I 12.5%  I        I
           NO             I        I        I        I
              2           I        I        I        I      4.0%
VAR(11)                   I      1 I      1 I        I        2
PT AND FAM ACCEPT RX      I--------I--------I--------I
                          I        I        I 44.4%  I
           UNAVAIL        I        I        I        I
              3           I        I        I        I      8.0%
                          I        I        I      4 I        4
                          I--------I--------I--------I

                  PERCENT    66.0%    16.0%    18.0%    100.0%
                  TOTAL       33        8        9        50

UPPER CELL ENTRIES ARE PERCENT OF COLUMN TOTALS

CHI-SQUARE                                 21.483***     SIGNIFICANCE UNDER .001
CRAMER'S V                                  0.464

TABLE SUMMARY

TOTAL NUMBER OF UNITS IN TABLE                               50
```

⑰

```
                                          VAR(13)
                                          INITIAL  S W EVALUATION

                                 YES       NO         UNAVAI
                                                      L
                                  1         2         3        TOTAL
                               I--------I--------I--------I
                               I 14.8%  I 21.4%  I        I
              YES              I        I        I        I
                 1             I        I        I        I   14.0%
                               I      4 I      3 I        I       7
                               I--------I--------I--------I
                               I 85.2%  I 78.6%  I 11.1%  I
              NO               I        I        I        I
                 2             I        I        I        I   70.0%
    VAR(12)                    I     23 I     11 I      1 I      35
    INIT PSYCH EVALUATION      I--------I--------I--------I
                               I        I        I 88.9%  I
              UNAVAIL          I        I        I        I
                 3             I        I        I        I   16.0%
                               I        I        I      8 I       8
                               I--------I--------I--------I

                        PERCENT   54.0%    28.0%    18.0%   100.0%
                        TOTAL       27       14        9       50
    UPPER CELL ENTRIES ARE PERCENT OF COLUMN TOTALS

    CHI-SQUARE                                      43.764***      SIGNIFICANCE U
    CRAMER'S V                                       0.662

    TABLE SUMMARY

    TOTAL NUMBER OF UNITS IN TABLE                                50
```

⑱

```
                                  VAR(14)
                                  INIT PREDIAL NURS EVAL

                         YES       NO         UNAVAI
                                              L
                          1         2         3        TOTAL
                       I--------I--------I--------I
                       I 18.2%  I 12.5%  I        I
          YES          I        I        I        I
             1         I        I        I        I   14.0%
                       I      6 I      1 I        I       7
                       I--------I--------I--------I
                       I 81.8%  I 87.5%  I 11.1%  I
          NO           I        I        I        I
             2         I        I        I        I   70.0%
VAR(12)                I     27 I      7 I      1 I      35
INIT PSYCH EVALUATION  I--------I--------I--------I
                       I        I        I 88.9%  I
          UNAVAIL      I        I        I        I
             3         I        I        I        I   16.0%
                       I        I        I      8 I       8
                       I--------I--------I--------I

                PERCENT   66.0%    16.0%    18.0%   100.0%
                TOTAL       33        8        9       50
UPPER CELL ENTRIES ARE PERCENT OF COLUMN TOTALS

CHI-SQUARE                                      43.557***      SIGNIFICANCE UNDER .001
CRAMER'S V                                       0.660

TABLE SUMMARY

TOTAL NUMBER OF UNITS IN TABLE                                50
```

⑲

```
                                        VAR(16)
                                        INIT EVAL DIETICIAN
                             YES       NO        UNAVAI
                                                 L
                              1         2        3         TOTAL
                           I-------I-------I-------I
        YES                I 78.8% I 71.4% I       I
            1              I       I       I       I
                           I       I       I       I   64.6%
                           I    26 I     5 I       I     31
                           I-------I-------I-------I
        NO                 I 15.2% I 28.6% I 12.5% I
             2             I       I       I       I
VAR(14)                    I       I       I       I   16.7%
INIT PREDIAL NURS EVAL     I     5 I     2 I     1 I     8
                           I-------I-------I-------I
        UNAVAIL            I  6.1% I       I 87.5% I
           3               I       I       I       I
                           I       I       I       I   18.8%
                           I     2 I       I     7 I     9
                           I-------I-------I-------I
                   PERCENT    68.8%    14.6%   16.7%   100.0%
                   TOTAL       33        7       8       48
UPPER CELL ENTRIES ARE PERCENT OF COLUMN TOTALS

CHI-SQUARE                                 31.296***      SIGNIFICANCE UNDER .001
CRAMER'S V                                  0.571

TABLE SUMMARY

TOTAL NUMBER OF UNITS IN TABLE                          48
NUMBER OF UNITS OMITTED DUE TO WILD SCORES               2
```

(20)

```
                                        VAR(16)
                                        INIT EVAL DIETICIAN
                             YES       NO        UNAVAI
                                                 L
                              1         2        3         TOTAL
                           I-------I-------I-------I
        YES                I 18.2% I 14.3% I       I
            1              I       I       I       I
                           I       I       I       I   14.6%
                           I     6 I     1 I       I     7
                           I-------I-------I-------I
        NO                 I 75.8% I 85.7% I 25.0% I
             2             I       I       I       I
VAR(12)                    I       I       I       I   68.8%
INIT PSYCH EVALUATION      I    25 I     6 I     2 I    33
                           I-------I-------I-------I
        UNAVAIL            I  6.1% I       I 75.0% I
           3               I       I       I       I
                           I       I       I       I   16.7%
                           I     2 I       I     6 I     8
                           I-------I-------I-------I
                   PERCENT    68.8%    14.6%   16.7%   100.0%
                   TOTAL       33        7       8       48
UPPER CELL ENTRIES ARE PERCENT OF COLUMN TOTALS

CHI-SQUARE                                 23.943***      SIGNIFICANCE UNDER .001
CRAMER'S V                                  0.499

TABLE SUMMARY

TOTAL NUMBER OF UNITS IN TABLE                          48
NUMBER OF UNITS OMITTED DUE TO WILD SCORES               2
```

(21)

74

(22)

```
                                   VAR(19)
                                   PSYCH SUIT TRPLANT NOTE

                         YES       NO        UNAVAI
                                             L
                          1         2        3         TOTAL
                        I--------I--------I--------I
                        I100.0%  I 19.4%  I        I
           YES          I        I        I        I
              1         I        I        I        I  26.7%
                        I       6I       6I        I   12
                        I--------I--------I--------I
                        I        I 90.6%  I        I
           NO           I        I        I        I
              2         I        I        I        I  55.6%
VAR(18)                 I        I      25I        I   25
MED SUIT TRPLANT NOTE   I--------I--------I--------I
                        I        I        I100.0%  I
           UNAVAIL      I        I        I        I
              3         I        I        I        I  17.8%
                        I        I        I       8I    8
                        I--------I--------I--------I

                 PERCENT  13.3%    68.9%    17.8%   100.0%
                 TOTAL      6       31        8       45

UPPER CELL ENTRIES ARE PERCENT OF COLUMN TOTALS

CHI-SQUARE                                63.145***     SIGNIFICANCE UNDER .001 WITH 4 DEGREES OF FREEDO
CRAMER'S V                                 0.838

TABLE SUMMARY

TOTAL NUMBER OF UNITS IN TABLE                                45
NUMBER OF UNITS OMITTED DUE TO BLANKS                          3
NUMBER OF UNITS OMITTED DUE TO WILD SCORES                     2
```

```
                                      CORRELATION COEFFICIENTS   ②

                                       VAR
VARIABLE DESCRIPTION     NAME          (17)
INIT EVAL DIETICIAN      VAR(16)      0.157

ALL CORRELATIONS BASED ON    40 UNITS.     10 BLANK UNITS OMITTED.
```

```
                                  VAR(34)
                                  DIET ORDER K NA FLU PRO

                         YES       NO       UNAVAI
                                            L
                          1         2       3        TOTAL
                       I-------I--------I-------I
                       I 93.3% I 22.2%  I 25.0% I
            YES        I       I        I       I
              1        I       I        I       I    68.1%
                       I    28 I      2 I     2 I     32
                       I-------I--------I-------I
                       I  3.3% I 66.7%  I       I
            NO         I       I        I       I
              2        I       I        I       I    14.9%
VAR(16)                I     1 I      6 I       I      7
INIT EVAL DIETICIAN    I-------I--------I-------I
                       I  3.3% I 11.1%  I 75.0% I
            UNAVAIL    I       I        I       I
              3        I       I        I       I    17.0%
                       I     1 I      1 I     6 I      8
                       I-------I--------I-------I

                PERCENT   63.8%    19.1%    17.0%   100.0%
                TOTAL      30        9        8       47

UPPER CELL ENTRIES ARE PERCENT OF COLUMN TOTALS

CHI-SQUARE                                47.138***     SIGNIFICANCE UNDER .001
CRAMER'S V                                 0.708

TABLE SUMMARY

TOTAL NUMBER OF UNITS IN TABLE                            47
NUMBER OF UNITS OMITTED DUE TO WILD SCORES                 3
```

(23)

```
                                  VAR(35)
                                  NOTE REG DIET RE PT DIET

                         YES       NO       UNAVAI
                                            L
                          1         2       3        TOTAL
                       I-------I-------I--------I
                       I 90.9% I 14.3% I 25.0%  I
            YES        I       I       I        I
              1        I       I       I        I    68.8%
                       I    30 I     1 I      2 I     33
                       I-------I-------I--------I
                       I  6.1% I 71.4% I        I
            NO         I       I       I        I
              2        I       I       I        I    14.6%
VAR(16)                I     2 I     5 I        I      7
INIT EVAL DIETICIAN    I-------I-------I--------I
                       I  3.0% I 14.3% I 75.0%  I
            UNAVAIL    I       I       I        I
              3        I       I       I        I    16.7%
                       I     1 I     1 I      6 I      8
                       I-------I-------I--------I

                PERCENT   68.8%    14.6%    16.7%   100.0%
                TOTAL      33        7        8       48

UPPER CELL ENTRIES ARE PERCENT OF COLUMN TOTALS

CHI-SQUARE                                45.964***     SIGNIFICANCE UNDER .001
CRAMER'S V                                 0.692

TABLE SUMMARY

TOTAL NUMBER OF UNITS IN TABLE                            48
NUMBER OF UNITS OMITTED DUE TO WILD SCORES                 2
```

(24)

```
                                                   CORRELATION COEFFICIENTS      (3)

                                                   VAR
VARIABLE DESCRIPTION        NAME                   (59)- Last S.W. Consults in Months
FREQ S W CONSULT            VAR(58)             -0.179

ALL CORRELATIONS BASED ON     42 UNITS.            8 BLANK UNITS OMITTED.        (4)


                                                       CC
                                                   VAR      Last Nepro Consult in Mos.
VARIABLE DESCRIPTION        NAME                   (63)
FREQ NEPHRO CONSULT         VAR(62)             -0.346*                  (5) (4)

ALL CORRELATIONS BASED ON     43 UNITS.            7 BL,

                                                   VAR                                  (5)
VARIABLE DESCRIPTION        NAME                   (57)     Last Psych Consult in Mos
FREQ PSYCH CONSULT          VAR(56)              0.001

ALL CORRELATIONS BASED ON     40 UNITS.           10 BLANK UNITS OMITTED.             (6)


                                                   VAR
VARIABLE DESCRIPTION        NAME                   (14)
LAST COMP NURS EVAL MOS     VAR(15)             -0.009

ALL CORRELATIONS BASED ON     47 UNITS.            3 BLANK UNITS OMITTED.
```

75

(25)

```
                                                  VAR(43)
                                                  FREQ PLATELET CT
                   WKLY    E 2 WK  E 3 WK  E MO    E 5 WK  E 6 WK  E7 WK   E 2 MO  E 9 WK  E 10 W  E 11 W  E 3 MO  LT E 3  UNAVAI
                                                                           S               K       K       S       MOS     L
                   1       2       3       4       5       6       7       8       9       10      11      12      13      14       TOTAL
                  I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------II-------I
  WKLY            I100.0% I       I       I 21.4% I       I       I       I       I       I       I       I       I       II       I  8.2%
   1              I     1 I       I       I     3 I       I       I       I       I       I       I       I       I       II       I    4
                  I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------II-------I
  E 2 WK          I       I100.0% I100.0% I  7.1% I 66.7% I 57.1% I       I       I       I       I       I       I       II 12.5% I 22.4%
   2              I       I     2 I     1 I     1 I     2 I     4 I       I       I       I       I       I       I       II     1 I   11
                  I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------II-------I
  E 3 WK          I       I       I       I  7.1% I       I 14.3% I 33.3% I       I       I       I       I       I       II       I  6.1%
   3              I       I       I       I     1 I       I     1 I     1 I       I       I       I       I       I       II       I    3
                  I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------II-------I
  E4WK            I       I       I       I 64.3% I       I 14.3% I 66.7% I100.0% I       I       I       I100.0% I 50.0% II       I 38.8%
   4              I       I       I       I     9 I       I     1 I     2 I     5 I       I       I       I     1 I     1 II       I   19
                  I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------II-------I
  E5 WK           I       I       I       I       I 33.3% I 14.3% I       I       I       I 50.0% I       I       I       II       I  6.1%
   5              I       I       I       I       I     1 I     1 I       I       I       I     1 I       I       I       II       I    3
VAR(42)           I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------II-------I
FREQUENCY CBC
  E6 WK           I       I       I       I       I       I       I       I       I       I       I       I       I       II       I  0.0%
   6              I       I       I       I       I       I       I       I       I       I       I       I       I       II       I    0
                  I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------II-------I
  E 7 WK          I       I       I       I       I       I       I       I       I       I       I       I       I       II       I  0.0%
   7              I       I       I       I       I       I       I       I       I       I       I       I       I       II       I    0
                  I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------II-------I
  E 2 MOS         I       I       I       I       I       I       I       I       I       I       I       I       I       II       I  0.0%
   8              I       I       I       I       I       I       I       I       I       I       I       I       I       II       I    0
                  I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------II-------I
  E 9 WK          I       I       I       I       I       I       I       I       I       I       I       I       I       II       I  0.0%
   9              I       I       I       I       I       I       I       I       I       I       I       I       I       II       I    0
                  I=======I=======I=======I=======I=======I=======I=======I-------I-------I-------I-------I-------I-------I========I
  E 10 WK         I       I       I       I       I       I       I       I       I 50.0% I       I       I       I       I       I  2.0%
   10             I       I       I       I       I       I       I       I       I     1 I       I       I       I       I       I    1
                  I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I
  E 11 WK         I       I       I       I       I       I       I       I       I       I       I       I       I       I       I  0.0%
   11             I       I       I       I       I       I       I       I       I       I       I       I       I       I       I    0
                  I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I
  E 3 MOS         I       I       I       I       I       I       I       I       I       I       I       I       I       I       I  0.0%
   12             I       I       I       I       I       I       I       I       I       I       I       I       I       I       I    0
VAR(42)           I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I
FREQUENCY CBC
  LT E 3 MOS      I       I       I       I       I       I       I       I       I       I       I       I       I       I       I  0.0%
   13             I       I       I       I       I       I       I       I       I       I       I       I       I       I       I    0
                  I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I
  UNAVAIL         I       I       I       I       I       I       I       I       I       I       I       I 50.0% I 87.5% I       I 16.3%
   14             I       I       I       I       I       I       I       I       I       I       I       I     1 I     7 I       I    8
                  I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I
          PERCENT     2.0%    4.1%    2.0%   28.6%    6.1%   14.3%    6.1%   10.2%    0.0%    4.1%    0.0%    2.0%    4.1%   16.3%  100.0%
          TOTAL       1       2       1      14       3       7       3       5       0       2       0       1       2       8      49
UPPER CELL ENTRIES ARE PERCENT OF COLUMN TOTALS

     CHI-SQUARE                        126.543***    SIGNIFICANCE UNDER .001 WITH 66 DEGREES OF FREEDOM
     CRAMER'S V                          0.657

     TABLE SUMMARY
```

76

(26)

```
                                                     VAR(42)
                                                     FREQUENCY CBC                                                        VAR(42)
               WKLY     E 2 WK   E 3 WK   E4WK     E5 WK    E6 WK    E 7 WK   E 2 MO   E 9 WK   E 10 W   E 11 W   E 3 MO   LT E 3    FREQUENCY CBC
                                                                              S                 K        K        S        MOS       UNAVAI
               1        2        3        4        5        6        7        8        9        10       11       12       13        L
                                                                                                                                     14         TOTAL
             I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------II--------I
E 1 WK       I 75.0%  I 45.5%  I        I  5.3%  I        I        I        I        I        I        I        I        I        II 12.5%  I
  1          I      3 I      5 I        I      1 I        I        I        I        I        I        I        I        I        II      1 I  20.4%
             I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------II--------I  10
E MO         I        I 54.5%  I 66.7%  I 78.9%  I 33.3%  I        I        I        I        I        I        I        I        II        I
  2          I        I      6 I      2 I     15 I      1 I        I        I        I        I        I        I        I        II        I  49.0%
             I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------II--------I  24
E 6 WK       I        I        I        I        I        I        I        I        I        I        I        I        I        II        I
  3          I        I        I        I        I        I        I        I        I        I        I        I        I        II        I   0.0%
             I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------II--------I   0
E 2   MOS    I        I        I        I  5.3%  I 33.3%  I        I        I        I        I        I        I        I        II        I
  4          I        I        I        I      1 I      1 I        I        I        I        I        I        I        I        II        I   4.1%
             I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------II--------I   2
E 10 WK      I        I        I        I  5.3%  I        I        I        I        I        I        I        I        I        II        I
  5          I        I        I        I      1 I        I        I        I        I        I        I        I        I        II        I   2.0%
(42)         I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------II--------I   1
O ELECTROLYTES
E 3 MOS      I        I        I        I        I        I        I        I        I        I        I        I        I        II        I
  6          I        I        I        I        I        I        I        I        I        I        I        I        I        II        I   0.0%
             I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------II--------I   0
E 14 WK      I        I        I        I        I 33.3%  I        I        I        I        I        I        I        I        II        I
  7          I        I        I        I        I      1 I        I        I        I        I        I        I        I        II        I   2.0%
             I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------II--------I   1
E 4 MOS      I        I        I 33.3%  I        I        I        I        I        I        I        I        I        I        II        I
  8          I        I        I      1 I        I        I        I        I        I        I        I        I        I        II        I   2.0%
             I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------II--------I   1
E 18 WK      I 25.0%  I        I        I  5.3%  I        I        I        I        I        I        I        I        I        II        I
  9          I      1 I        I        I      1 I        I        I        I        I        I        I        I        I        II        I   4.1%
             I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------II--------I   2
UNAVAIL      I        I        I        I        I        I        I        I        I100.0%  I        I        I        II 87.5%  I
  10         I        I        I        I        I        I        I        I        I      1 I        I        I        II      7 I  16.3%
(42)         I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------II--------I   8
O ELECTROLYTES
PERCENT         8.2%    22.4%     6.1%    38.8%     6.1%     0.0%     0.0%     0.0%     0.0%     2.0%     0.0%     0.0%     0.0% I   16.3%   100.0%
TOTAL             4       11        3       19        3        0        0        0        0        1        0        0        0 I      8       49

UPPER CELL ENTRIES ARE PERCENT OF COLUMN TOTALS
CHI-SQUARE                          104.051***     SIGNIFICANCE UNDER .001
CRAMER'S V                            0.595

TABLE SUMMARY
```

77

```
                                                    CROSSTAB NO.  19                                              PAGE  1-
                                                           VAR(40)
                                                           FREQUENCY K
                              GT=ONE   F WK     F 2 WK  E 3WK    E MO     E5 WK    F 6 WK   F 2 MO   E LTE    UNAVAI
                               WK                                                          S        2 MOS    L        TOTAL
                              1        2        3        4        5        6        7        8        9        10
                            I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I
                            I        I 50.0%  I 53.3%  I        I        I        I        I        I        I        I
            F 1 WK          I        I        I        I        I        I        I        I        I        I        I  20.0%
                1           I        I      2 I      8 I        I        I        I        I        I        I        I   10
                            I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I
                            I        I 50.0%  I 26.7%  I100.0%  I 73.3%  I 50.0%  I        I        I        I        I
            E MO            I        I        I        I        I        I        I        I        I        I        I  48.0%
                2           I        I      2 I      4 I      6 I     11 I      1 I        I        I        I        I   24
                            I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I
            F 6 WK          I        I        I        I        I        I        I        I        I        I        I   0.0%
                3           I        I        I        I        I        I        I        I        I        I        I    0
                            I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I
                            I        I        I        I        I 13.3%  I        I        I        I        I        I
            F 2   MOS       I        I        I        I        I        I        I        I        I        I        I   4.0%
                4           I        I        I        I        I      2 I        I        I        I        I        I    2
                            I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I
                            I        I        I        I        I  6.7%  I        I        I        I        I        I
            F 10 WK         I        I        I        I        I        I        I        I        I        I        I   2.0%
                5           I        I        I        I        I      1 I        I        I        I        I        I    1
VAR(49)                     I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I
FREQ ELECTROLYTES
            F 3 MOS         I        I        I        I        I        I        I        I        I        I        I   0.0%
                6           I        I        I        I        I        I        I        I        I        I        I    0
                            I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I
                            I        I        I        I        I        I 50.0%  I        I        I        I        I
            F 14 WK         I        I        I        I        I        I        I        I        I        I        I   2.0%
                7           I        I        I        I        I        I      1 I        I        I        I        I    1
                            I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I
                            I        I        I  6.7%  I        I        I        I        I        I        I        I
            F 4 MOS         I        I        I        I        I        I        I        I        I        I        I   2.0%
                8           I        I        I      1 I        I        I        I        I        I        I        I    1
                            I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I
                            I        I        I 13.3%  I        I        I        I        I        I        I        I
            F 18 WK         I        I        I        I        I        I        I        I        I        I        I   4.0%
                9           I        I        I      2 I        I        I        I        I        I        I        I    2
                            I--------I--------I--------I========I========I========I========I========I========I========I
                            I        I        I        I        I  6.7%  I        I        I        I        I100.0%  I
            UNAVAIL         I        I        I        I        I        I        I        I        I        I        I  18.0%
               10           I        I        I        I        I      1 I        I        I        I        I      8 I    9
VAR(49)                     I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I
FREQ ELECTROLYTES
                 PERCENT      0.0%     8.0%    30.0%    12.0%    30.0%     4.0%     0.0%     0.0%     0.0%    16.0%  100.0%
                 TOTAL         0        4       15        6       15        2        0        0        0        8      50

UPPER CELL ENTRIES ARE PERCENT OF COLUMN TOTALS

CHI-SQUARE                                  100.801***      SIGNIFICANCE UNDER .001 WITH 35 DEGREES OF FREEDOM
CRAMER'S V                                    0.635

TABLE SUMMARY
TOTAL NUMBER OF UNITS IN TABLE                     50
```

78

(28)

VAR(41)
FREQUENCY BUN CREAT

VAR(40) FREQ ELECTROLYTES	WKLY 1	F 2 WK 2	F 3 WK 3	E MONTH 4	E 5 WK 5	E 6 WK 6	E 7 WK 7	E 8 WK 8	LT E 2 MOS 9	UNAVAIL 10	TOTAL
F 1 WK 1		72.7% 8		8.7% 2							20.0% 10
F MO 2		27.3% 3	100.0% 4	69.6% 16	50.0% 1						48.0% 24
F 6 WK 3											0.0% 0
F 2 MOS 4				4.3% 1		50.0% 1					4.0% 2
F 10 WK 5				4.3% 1							2.0% 1
F 3 MOS 6											0.0% 0
F 14 WK 7						50.0% 1					2.0% 1
F 4 MOS 8				4.3% 1							2.0% 1
F 18 WK 9				6.7% 2							4.0% 2
UNAVAIL 10					50.0% 1					100.0% 8	18.0% 9
PERCENT TOTAL	0.0% 0	22.0% 11	8.0% 4	46.0% 23	4.0% 2	4.0% 2	0.0% 0	0.0% 0	0.0% 0	16.0% 8	100.0% 50

UPPER CELL ENTRIES ARE PERCENT OF COLUMN TOTALS

CHI-SQUARE 108.733*** SIGNIFICANCE UNDER .001 WITH 35 DEGREES OF FREEDOM
CRAMER'S V 0.659

TABLE SUMMARY

TOTAL NUMBER OF UNITS IN TABLE 50

```
                                               VAR(37)
                                               FREQ ALK PHOS
                 GT ONC   ONC A    E 2 WK   E 3 WK   E MO     E 2 MO   E3 MOS   E 3MOS   UNAVAI
                 WK       WK                                  S                          L
                 1        2        3        4        5        6        7        8        9        TOTAL
                I--------I--------I--------I--------I--------I--------I--------I--------I--------I
                I        I        I        I        I        I        I        I        I        I
GT ONC WK       I        I        I        I        I        I        I        I        I        I
   1            I        I        I        I        I        I        I        I        I        I    0.0%
                I        I        I        I        I        I        I        I        I        I      0
                I--------I--------I--------I--------I--------I--------I--------I--------I--------I
                I        I        I  50.0% I   6.1% I        I        I        I        I        I
ONC A WK        I        I        I        I        I        I        I        I        I        I
   2            I        I        I        I        I        I        I        I        I        I    6.0%
                I        I        I       1I       2I        I        I        I        I        I      3
                I--------I--------I--------I--------I--------I--------I--------I--------I--------I
                I        I        I        I  21.2% I  50.0% I        I        I        I        I
E 2 WK          I        I        I        I        I        I        I        I        I        I
   3            I        I        I        I        I        I        I        I        I        I   16.0%
                I        I        I        I       7I       1I        I        I        I        I      8
                I--------I--------I--------I--------I--------I--------I--------I--------I--------I
                I        I        I        I   3.0% I        I        I        I        I        I
E 3 WK          I        I        I        I        I        I        I        I        I        I
   4            I        I        I        I        I        I        I        I        I        I    2.0%
                I        I        I        I       1I        I        I        I        I        I      1
                I--------I--------I--------I--------I--------I--------I--------I--------I--------I
                I        I        I  50.0% I  66.7% I  50.0% I  66.7% I        I 100.0% I        I
E MO            I        I        I        I        I        I        I        I        I        I
   5            I        I        I        I        I        I        I        I        I        I   54.0%
A PO            I        I        I       1I      22I       1I       2I        I       1I        I     27
                I--------I--------I--------I--------I--------I--------I--------I--------I--------I
                I        I        I        I        I        I  33.3% I 100.0% I        I        I
E 2 MOS         I        I        I        I        I        I        I        I        I        I
   6            I        I        I        I        I        I        I        I        I        I    6.0%
                I        I        I        I        I        I       1I       2I        I        I      3
                I--------I--------I--------I--------I--------I--------I--------I--------I--------I
                I        I        I        I        I        I        I        I        I        I
E3 MOS          I        I        I        I        I        I        I        I        I        I
   7            I        I        I        I        I        I        I        I        I        I    0.0%
                I        I        I        I        I        I        I        I        I        I      0
                I--------I--------I--------I--------I--------I--------I--------I--------I--------I
                I        I        I        I   3.0% I        I        I        I        I        I
E 3MOS          I        I        I        I        I        I        I        I        I        I
   8            I        I        I        I        I        I        I        I        I        I    2.0%
                I        I        I        I       1I        I        I        I        I        I      1
                I--------I--------I--------I--------I--------I--------I--------I--------I--------I
                I        I        I        I        I        I        I        I        I 100.0% I
UNAVAIL         I        I        I        I        I        I        I        I        I        I
   9            I        I        I        I        I        I        I        I        I        I   14.0%
                I        I        I        I        I        I        I        I        I       7I      7
                I--------I--------I--------I--------I--------I--------I--------I--------I--------I
 PO

        PERCENT    0.0%     0.0%     4.0%    66.0%     4.0%     6.0%     4.0%     2.0%    14.0%   100.0%
        TOTAL        0        0        2       33        2        3        2        1        7       50
ARE                            98.011***     SIGNIFICANCE UNDER .001 WITH 36 DEGREES OF FREEDOM
S V                             0.572

UMMARY

UMBER OF UNITS IN TABLE                      50
```

(30)

VAR(44)
FREQUENCY SGOT OR PT

	WKLY 1	E 2 WK 2	E 3 WK 3	E MO 4	E 5 WK 5	E 6 WK 6	E7 WK 7	E 2 MOS 8	E 9 WK 9	E 10 WK 10	E 11 WK 11	E 3 MOS 12	LT E 3 MOS 13	UNAVAIL 14	TOTAL
GT ONE WK 1															0.0% 0
ONC A WK 2															0.0% 0
E 2 WK 3		50.0% 1		4.0% 1											4.2% 2
E 3 WK 4		50.0% 1	50.0% 1	88.0% 22			100.0% 1	100.0% 2						33.3% 4	64.6% 31
E MO 5			50.0% 1	4.0% 1											4.2% 2
E 2 MOS 6				4.0% 1	100.0% 1	100.0% 1									6.3% 3
E3 MOS 7									100.0% 1			100.0% 1			4.2% 2
E 3MOS 8														8.3% 1	2.1% 1
UNAVAIL 9														58.3% 7	14.6% 7
PERCENT TOTAL	0.0% 0	4.2% 2	4.2% 2	52.1% 25	2.1% 1	2.1% 1	2.1% 1	4.2% 2	2.1% 1	0.0% 0	0.0% 0	2.1% 1	0.0% 0	25.0% 12	100.0% 48

1371
ALK PHOS

ER CELL ENTR

CHI-SQUARE 128.795*** SIGNIFICANCE UNDER .001 WITH 54 DEGREES OF FREEDOM
CRAMER'S V 0.669

TABLE SUMMARY

TOTAL NUMBER OF UNITS IN TABLE 48
NUMBER OF UNITS OMITTED DUE TO BLANKS 2

VAR(45)
FREQUENCY AA ON PTS

VAR(45)
FREQUENCY AA I

	WKLY 1	E 2 WK 2	E.3 WK 3	E MO 4	E 5 WK 5	E 6 WK 6	E7 WK 7	E 2 MOS 8	E 9 WK 9	E 10 WK 10	E 11 WK 11	E 3 MOS 12	LT E 3 MOS 13	UNAVAIL 14	TOTAL
GT ONE WK 1															0.0% 0
ONE A WK 2															0.0% 0
E 2 WK 3				7.1% 2											4.0% 2
E 3 WK 4			75.0% 3	78.6% 22	75.0% 3	100.0% 2					100.0% 1			22.2% 2	66.0% 33
E MO 5				3.6% 1	25.0% 1										4.0% 2
E 2 MOS 6			25.0% 1	7.1% 2											6.0% 3
E3 MOS 7				3.6% 1								100.0% 1			4.0% 2
E 3MOS 8									100.0% 1						2.0% 1
UNAVAIL 9														77.8% 7	14.0% 7
PERCENT TOTAL	0.0% 0	0.0% 0	8.0% 4	56.0% 28	8.0% 4	4.0% 2	0.0% 0	0.0% 0	2.0% 1	0.0% 0	2.0% 1	2.0% 1	0.0% 0	18.0% 9	100.0% 50

LK PHOS

LK PHOS

CHI-SQUARE 120.271*** SIGNIFICANCE UNDER .001 WITH 42 DEGREES OF FREEDOM
CRAMER'S V 0.633

TABLE SUMMARY

TOTAL NUMBER OF UNITS IN TABLE 50

83

(32)

VAR(45)
FREQUENCY AA ON PTS

VAR(44) FREQUENCY SGOT OR PT	WKLY 1	E 2 WK 2	E 3 WK 3	E MO 4	E 5 WK 5	E 6 WK 6	E7 WK 7	E 2 MOS 8	E 9 WK 9	E 10 WK 10	E 11 WK 11	E 3 MOS 12	LT E 3 MOS 13	UNAVAIL 14	TOTAL
WKLY 1															0.0% 0
E 2 WK 2				3.7% 1							100.0% 1				4.2% 2
E 3 WK 3			25.0% 1		25.0% 1										4.2% 2
E MO 4			50.0% 2	74.1% 20	25.0% 1	100.0% 1								11.1% 1	52.1% 25
E 5 WK 5			25.0% 1												2.1% 1
E 6 WK 6				3.7% 1											2.1% 1
E7 WK 7					25.0% 1										2.1% 1
E 2 MOS 8				3.7% 1	25.0% 1										4.2% 2
E 9 WK 9				3.7% 1											2.1% 1
E 10 WK 10															0.0% 0
E 11 WK 11															0.0% 0
E 3 MOS 12												100.0% 1			2.1% 1
LT E 3 MOS 13															0.0% 0
UNAVAIL 14				11.1% 3					100.0% 1					88.9% 8	25.0% 12
PERCENT TOTAL	0.0% 0	0.0% 0	8.3% 4	56.3% 27	8.3% 4	2.1% 1	0.0% 0	0.0% 0	2.1% 1	0.0% 0	2.1% 1	2.1% 1	0.0% 0	18.8% 9	100.0% 48

UPPER CELL ENTRIES ARE PERCENT OF COLUMN TOTALS

CHI-SQUARE 138.080*** SIGNIFICANCE UNDER .001
CRAMER'S V 0.641

TABLE SUMMARY

```
                                        VAR(39)
                                        PT HAVE BONE FRAX

                               YES      NO       UNAVAIL
                                                 L
                               1        2        3         TOTAL
                          I--------I--------I--------I
            YES           I        I 10.5%  I        I
              1           I        I        I        I      8.0%
                          I        I      4 I        I        4
                          I--------I--------I--------I
            NO            I 83.3%  I 86.8%  I 16.7%  I
              2           I        I        I        I
VAR(38)                   I        I        I        I     78.0%
RISE ALK PHOS 50%         I      5 I     33 I      1 I       39
                          I--------I--------I--------I
                          I 16.7%  I  2.6%  I 83.3%  I
            UNAVAIL       I        I        I        I
              3           I        I        I        I     14.0%
                          I      1 I      1 I      5 I        7
                          I--------I--------I--------I
                    PERCENT  12.0%    76.0%    12.0%    100.0%
                    TOTAL      6        38       6         50
UPPER CELL ENTRIES ARE PERCENT OF COLUMN TOTALS

CHI-SQUARE                                  28.700***     SIGNIFICANCE UNDER .001 WITH 4 DEGREES
CRAMER'S V                                   0.536

TABLE SUMMARY

TOTAL NUMBER OF UNITS IN TABLE                                    50
```

80

```
                                        VAR(38)
                                        RISE ALK PHOS 50%

                              YES        NO        UNAVAIL
                                                   L
                               1          2         3        TOTAL
                          I---------I---------I---------I
           GT ONC WK      I         I         I         I
              1           I         I         I         I
                          I         I         I         I    0.0%
                          I         I         I         I      0
                          I---------I---------I---------I
           ONC A WK       I         I         I         I
               2          I         I         I         I
                          I         I         I         I    0.0%
                          I         I         I         I      0
                          I---------I---------I---------I
           E 2 WK         I  25.0%  I   2.6%  I         I
               3          I         I         I         I
                          I         I         I         I    4.0%
                          I       1 I       1 I         I      2
                          I---------I---------I---------I
           E 3 WK         I  75.0%  I  76.9%  I         I
               4          I         I         I         I
                          I         I         I         I   66.0%
                          I       3 I      30 I         I     33
                          I---------I---------I---------I
           E MO           I         I   5.1%  I         I
               5          I         I         I         I
VAR(37)                   I         I         I         I    4.0%
FREQ ALK PHOS             I         I       2 I         I      2
                          I---------I---------I---------I
           E 2 MOS        I         I   7.7%  I         I
               6          I         I         I         I
                          I         I         I         I    6.0%
                          I         I       3 I         I      3
                          I---------I---------I---------I
           E3 MOS         I         I   5.1%  I         I
               7          I         I         I         I
                          I         I         I         I    4.0%
                          I         I       2 I         I      2
                          I---------I---------I---------I
           E 3MOS         I         I   2.6%  I         I
               8          I         I         I         I
                          I         I         I         I    2.0%
                          I         I       1 I         I      1
                          I---------I---------I---------I
           UNAVAIL        I         I         I 100.0%  I
               9          I         I         I         I
                          I         I         I         I   14.0%
                          I         I         I       7 I      7
VAR(37)                                       I---------I
FREQ ALK PHOS

                 PERCENT      8.0%      78.0%      14.0%    100.0%
                 TOTAL         4         39          7        50
CHI-SQUARE
CRAMER'S V
                                                55.521***
                                                 0.745

TABLE SIGNIFICANCE UNDER .001 WITH

           12 DEGREES OF FREEDOM
```

(34)

85

(35)

```
                                                               VAR(54)
                                                               FREQUENCY PTH
                  F MO     F 2 MO   E 3 MO   E 4 MO   E 5 MO   F 6 MO   F7 MOS   E 8 MO   E 9 MO   LE E 1   NON DR   UNAVAI
                                                               S                 S        S        0 MOS    AWN      L
                  1        2         3        4        5        6        7        8        9        10       11       12       TOTAL
                I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I
   GT ONC WK    I        I        I        I        I        I        I        I        I        I        I        I        I
       1        I        I        I        I        I        I        I        I        I        I        I        I        I  0.0%
                I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I   0
   ONC A WK     I        I        I        I        I        I        I        I        I        I        I        I        I
       2        I        I        I        I        I        I        I        I        I        I        I        I        I  0.0%
                I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I   0
   F 2 WK       I        I        I        I        I 20.0%  I        I        I        I        I        I        I        I
       3        I        I        I        I        I        I        I        I        I        I        I        I        I  4.2%
                I        I        I        I        I      2 I        I        I        I        I        I        I        I   2
                I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I
   F 3 WK       I        I        I 100.0% I        I 70.0%  I        I        I        I 63.6%  I 71.4%  I 45.5%  I
       4        I        I        I        I        I        I        I        I        I        I        I        I        I  64.6%
                I        I        I      2 I        I      7 I        I        I        I      7 I     10 I      5 I   31
                I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I
   F MO         I        I        I        I        I 10.0%  I        I        I        I        I  7.1%  I        I
       5        I        I        I        I        I        I        I        I        I        I        I        I        I  4.2%
VAR(37)         I        I        I        I        I      1 I        I        I        I        I      1 I        I   2
FREQ ALK PHOS   I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I
   E 2 MOS      I        I        I        I        I        I        I        I        I 18.2%  I  7.1%  I        I
       6        I        I        I        I        I        I        I        I        I        I        I        I        I  6.3%
                I        I        I        I        I        I        I        I        I      2 I      1 I        I   3
                I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I
   F3 MOS       I        I        I        I        I        I        I        I        I        I 14.3%  I        I
       7        I        I        I        I        I        I        I        I        I        I        I        I        I  4.2%
                I        I        I        I        I        I        I        I        I        I      2 I        I   2
                I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I
   F 3MOS       I        I        I        I        I        I        I        I        I  9.1%  I        I        I
       8        I        I        I        I        I        I        I        I        I        I        I        I        I  2.1%
                I        I        I        I        I        I        I        I        I      1 I        I        I   1
                I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I
   UNAVAIL      I        I        I        I        I        I        I        I        I  9.1%  I        I 54.5%  I
       9        I        I        I        I        I        I        I        I        I        I        I        I        I  14.6%
                I        I        I        I        I        I        I        I        I      1 I        I      6 I   7
                I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I--------I
       PERCENT    0.0%     0.0%     0.0%     4.2%     0.0%    20.8%     0.0%     0.0%     0.0%    22.9%    29.2%    22.9%   100.0%
       TOTAL       0        0        0        2        0       10        0        0        0       11       14       11      48

CHI-SQUARE                          39.121*     SIGNIFICANT AT .028 WITH 24 DEGREES OF FREEDOM
CRAMER'S V                           0.451

TABLE SUMMARY

TOTAL NUMBER OF UNITS IN TABLE                48
```

```
                                                            VAR(48)
                                                            FREQ FE BINDING CAPACITY
                     E 1 WK  E MO    E 6 WK  E 2     E 10 W  E 3 MO  E 14 W  E 4 MO  E 18 W  UNAVAI
                                             MOS     K       S       K       S       K       L
                     1       2       3       4       5       6       7       8       9       10       TOTAL
                    I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I
                    I       I       I       I       I       I       I       I       I       I       I
          E 1 WK    I       I       I       I       I       I       I       I       I       I       I
              1     I       I       I       I       I       I       I       I       I       I       I    0.0%
                    I       I       I       I       I       I       I       I       I       I       I      0
                    I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I
                    I       I 83.3% I       I       I       I       I       I       I       I       I
          E MO      I       I       I       I       I       I       I       I       I       I       I
              2     I       I       I       I       I       I       I       I       I       I       I   10.2%
                    I       I     5 I       I       I       I       I       I       I       I       I      5
                    I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I
                    I       I       I       I       I       I       I       I       I       I       I
          E 6 WK    I       I       I       I       I       I       I       I       I       I       I
              3     I       I       I       I       I       I       I       I       I       I       I    0.0%
                    I       I       I       I       I       I       I       I       I       I       I      0
                    I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I
                    I       I 16.7% I       I100.0% I       I       I       I       I 3.4%  I       I
          E 2   MOS I       I       I       I       I       I       I       I       I       I       I
              4     I       I       I       I       I       I       I       I       I       I       I    6.1%
                    I       I     1 I       I     1 I       I       I       I       I     1 I       I      3
                    I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I
                    I       I       I       I       I100.0% I       I       I       I       I       I
          E 10 WK   I       I       I       I       I       I       I       I       I       I       I
              5     I       I       I       I       I       I       I       I       I       I       I    2.0%
VAR(47)             I       I       I       I       I     1 I       I       I       I       I       I      1
FREQUENCY SERUM FE  I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I
                    I       I       I       I       I       I100.0% I       I       I       I       I
          E 3 MOS   I       I       I       I       I       I       I       I       I       I       I
              6     I       I       I       I       I       I       I       I       I       I       I    2.0%
                    I       I       I       I       I       I     1 I       I       I       I       I      1
                    I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I
                    I       I       I       I       I       I       I       I       I       I       I
          E 14 WK   I       I       I       I       I       I       I       I       I       I       I
              7     I       I       I       I       I       I       I       I       I       I       I    0.0%
                    I       I       I       I       I       I       I       I       I       I       I      0
                    I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I
                    I       I       I       I       I       I       I       I       I       I       I
          E 4 MOS   I       I       I       I       I       I       I       I       I       I       I
              8     I       I       I       I       I       I       I       I       I       I       I    0.0%
                    I       I       I       I       I       I       I       I       I       I       I      0
                    I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I
                    I       I       I       I       I       I       I       I       I 89.7% I 18.2% I
          E 18 WK   I       I       I       I       I       I       I       I       I       I       I
              9     I       I       I       I       I       I       I       I       I       I       I   57.1%
                    I       I       I       I       I       I       I       I       I    26 I     2 I     28
  --          -     I=======I=======I=======I=======I=======I=======I=======I=======I=======I=======I
                    I       I       I       I       I       I       I       I       I  6.9% I 81.8% I
          UNAVAIL   I       I       I       I       I       I       I       I       I       I       I
             10     I       I       I       I       I       I       I       I       I       I       I   22.4%
VAR(47)             I       I       I       I       I       I       I       I       I     2 I     9 I     11
FREQUENCY SERUM FE  I-------I-------I-------I-------I-------I-------I-------I-------I-------I-------I

           PERCENT    0.0%   12.2%    0.0%    2.0%    2.0%    2.0%    0.0%    0.0%   59.2%   22.4%  100.0%
           TOTAL       0       6       0       1       1       1       0       0      29      11      49

UPPER CELL ENTRIES ARE PERCENT OF COLUMN TOTALS

CHI-SQUARE                                 184.297***     SIGNIFICANCE UNDER .001 WITH 25 DEGREES OF FREEDOM
CRAMER'S V                                   0.867

TABLE SUMMARY

TOTAL NUMBER OF UNITS IN TABLE                          49
NUMBER OF UNITS OMITTED DUE TO WILD SCORES               1
```

COMMENTS AND RECOMMENDATIONS

Several of the problems germane to the use of medical records for quality of care assessment are highlighted by this study. The most important the "discrepancy" between chart documentation vs. the practice of medicine and vs. the practice of allied health professional's services. The non-optimal habits of the M.D. in chart documentation appear to have been followed, perhaps copies, by the other health professionals. When I visited the various facilities I was impressed by the consistency with which many categories of professionals comprehended the situation. Few gave me the impression that they believed changing their habits would have an impact on the actual rendering of care and some stated simply that more documentation would mean less patient care. I have some "healthy" skepticism but I also appreciate that the medical record is the basis for much of the information utilized by consultants and by successive managers of a patient. A cavalier attitude is unjustifiable because errors of omission have been known to result in errors of commission.

The role of the federal government in financing health care and its willingness to exert some control can no longer be ignored. Its intent to do so, and to use the medical record as the basis for its review is now about 13 years old and not likely to wave as the nation moves ever so slowly towards the government funding or establishing the mechanisms to provide more and more of the

health care services rendered. The fact that documentation tends to be uniformly good or bad has some significant ramifications for the latter should the federal government get really "hard-nose" about the issue. The premonitory signs are already sending people to jail for abuse or apparent abuse of the government's heretofore easy disposition.

The percent documentation rates listed in this study clearly demonstrates that there is considerable room for improvement in this area in the facilities studies and probably for the network. One cannot help but conjecture how the layman who writes the laws and files the suits would react to the sensational presentation of this raw data without expository statements. Certainly it would not generate the sort of publicity that would endear any of the health professionals to the general public or to the fed's funding agency. In fact, it could have significant repercussions for the funding of programs and also stimulate an uncontrollable proliferation of commode quality literature.

The autonomy of professionals is often touted as necessary for optimal treatment of patients by confident independently concerned professionals, but little team work appears to be manifest via chart documentation. In fact, the potential pivot role of the M.D. as patient manager as assigned by the legislation and underscored by this study appears to be lost in the grey-zone

between autonomy of another professional and the need for leadership as well as coordination to assure a unified assault on the problem. The situation is comparable to too many captains, on too many boats vaguely reminiscent of Pearl Harbor.

The problem of missing charts or widely dispersed documentation also figured prominently in the results of this study. I often had to consult four or five sources of information ostensibly referred to as the patients medical record. Consequently, a laborious task became exasperating and frankly burdensome. The cost to all of us as consumers would be astronomical if professionals had to spend as much of their time waiting as I. I must state that the cooperation that I received in locating all the information I needed was good to excellent, but I question the need for such organized disorganization. Parenthetically, I might add that Dr. Gelfman's record keeping system and St. Raphael's nursing summary reports are worthwhile investigating for network-wide usage.

Another problem, that of averages and the impact of acute episodes on the frequency of parameters supposedly assessing the routine quality of care made me appreciate the need for differentiating between acute and long-term routine management of patients in order to get the most representative data pertaining to the latter which may be markedly skewed by the former. I did not differentiate between the two and I have no appreciation

for the magnitude of this potential impact on my data. The fact that the frequencies presented are consistent with generally accepted medical practice for many of the dialysis assessment parameters may indicate that an averaging out effect occurs. This is no consolation because the frequency of patients receiving insufficient care is lost when only the aggregate data is viewed as might occur when it is perused by the uninitiated.

The problem of diagnostic specificity presented in a unique manner for this study. Many patients with E.S.R.D. had E.S.R.D. of uncertain eitiology and logically were spared the physical and emotional expense of a work-up because it would often be fruitless and not affect their treatment. Unfortunately, however, no prognostication about potential users can be gleaned from this approach.

The rate of documentation of the patients' resource (lab) consumption was better than that of the professionals. The facilities I visited were only 5 out of 14 in the State and one could easily postulate that they are amongst the better facilities because of the resources available to them (at least 3 affiliated with a major university complex). The profile analysis of these facilities are ample fuel for an active mind to speculate on the quality of care of their patients as well as the quality of documentation and the "attendant" quality of care of the less "sophisticated" facilities.

Much of these comments have admittedly pointed to potential weaknesses in the Connecticut E.S.R.D. patient services. Perhaps if politics, time and money had been more cooperative a more reliable indication of what is going on not only in the facilities studied but the State would have been possible.

I strongly recommend that the M.R.B. look into the area where poor documentation was described in the results and discussion of this study not just into the facilities studied but on a statewide level. I also strongly recommend a statewide study of greater sophistication with respect to acute and chronic treatment be undertaken in an attempt to get more refined, truely representative data using the instrument described herein with the appropriate modifications or a similar one. I suggest that some instrument for accurately defining the transplant decision tree, and home dialysis exclusion decision tree be developed and lastly I urge the M.D.'s not to give the impression that they are abandoning or are ill-suited for the leadership-coordinator role.

In closing I would like to say (1) autonomy is not a synonym for lack of accountability; (2) this instrument does show gross lack of documentation and failure to achieve stated guidelines; (3) statewide use of this instrument is a valid starting point to isolate and identify critical problems.

FOOTNOTES

1. Network Coordinating Council #27 response to the California regional medical program project report to Roy Crystal, E.S.R.D. program director; p. 1.

2. Ibid., p. 3.

3. Richard Rettig, Valving lives: The Policy Debate on Patient Care Financing for Victims of End-Stage Renal Disease; (The Rand Corporation: 1976), p. 3.

4. Richard Rettig, Lessons Learned from the End-Stage Renal Disease Experience (Boston University: 1976), p. 2.

5. Ibid., p. 6.

6. Ibid., p. 3.

7. Ibid., p. 12.

8. Ibid., p. 14.

9. Elia Friedman, et al., "Pragmatic Realities in Uremia Therapy," NEJM (Special Articles) 298:7, p. 370.

10. Ibid., p. 369.

11. Ibid., p. 370.

12. N. L. Tilney, et.al., "Treatment of Chronic Renal Failure by Transplantation and Dialysis: Two decades of Cooperation," Annals Surgery, 182:2, p.

13. Op. Cit., Friedman, p. 368.

14. Op. Cit., Rettig, Valving Lives, p. 14.

15. Op Cit., Tilney et.al., p. 110.

16. Ibid., p. 110.

17. The Tenth Report of the Human Renal Transplant Registry, JAMA (1973), 221:1495.

18. T. J. Stranova, et.al., "Chronic Hemodialysis in Connecticut," Connecticut Medicine (July 1974), p. 370.

19. D. A. Pearson, et.al., Characteristics of Connecticut Patients Receiving Services for End-Stage Uremia, Public Health Reports 90 (Sept., Oct., 1975):5, p. 444.

20. Ibid., p. 445.

21. Ibid., p. 446.

22. Ibid., p. 442.

23. Ibid., p. 442.

24. Op. Cit., Stranova, p. 372.

25. Op. Cit., Rettig, Valving Lives, p. 13.

26. Ibid., pp. 22-23.

27. Ibid., p. 27.

28. Ibid., p. 27.

29. Ibid., p. 32.

30. Richard A. Rettig, Implementation of the E.S.R.D. program A Mixed Pattern of Subsidizing Regulating the Delivery of Medical Services, (San Francisco: Annual Meeting of American Polical Scientist, Sept., Oct. 1975), pp. 2-3.

31. Ibid., pp. 16-17.

32. Rex B. Conn, "Clinical Laboratories: Profit Center Production Industry or Patient Care Resources?", NEJM 298 (Feb. 23, 1978): 8, p. 422.

33. Lynda D. Bayden, "The End-Stage Renal Disease Network," Medical Care XV (July 1977): 7, p. 589.

34. Op. Cit., Rettig, Valving Lives, p. 38.

35. DHEW draft dated 6/22/77 to PSRO and E.S.R.D. Directors and Coordinators re: Integration of E.S.R.D. M.R.B.'s with PSRO Review function.

36. DHEW Social Security Amendments, "Renal Disease: Implementation of Coverage of Suppliers of End Stage Services," Federal Register #7 (June 3, 1976), p. 22502.

37. Ibid., p. 22517.

38. Op. Cit., Rettig, Background Papers, p. 11.

39. Ibid., p. 17.

40. Paul V. Stange, et.al., "Predicting Treatment Cost and Life Expectancy for End Stage Renal Disease," NEJM 298 (Feb. 16, 1978):7, p. 372.

41. End Stage Renal Disease Program Guidelines: Chapter 301, Introduction to Medical Review (BQA-DHEW).

42. Ibid., p. 2.

43. R. H. Brook, et.al., Quality of Medical Care Assessment Using Outcome Measures: An Overview of the Method (R2021/1-HEW), Rand Corporation, 1976.

44. Op. Cit., E.S.R.D. Program Guidelines, p. 5.

45. John J. Williamson, "Formulating Priorities for Quality Assurance Activity: Description of a Method and its Application, JAMA 239 (Feb. 13, 1978): 7, p. 632.

46. Op. Cit., E.S.R.D. Program Guidelines Sec. 303-40.

47. David Kessner, "Quality Assessment and Assurance: Early Signs of Cognitive Dissonance," NEJM 298 (Feb. 1978): 7, p. 383.

48. Op. Cit., End Stage Renal Disease Program Guidelines Sec. 303-22.

49. Op. Cit., Kessner, p. 384.

50. Guidelines for Nutritional Care of E.S.R.D. Patients, Included in Letter Correspondence Committee of Nephrology S.W., to Dr. Paul Doolan, Quality of Care Subcommittee, Chairman E.S.R.D. Network #27.

51. Ibid.

BIBLIOGRAPHY

1. Vol. 41 Federal Register No. 108 Part II, Thursday, 6/3/76; DHEW SS Administration: Renal Disease, Implementation of Coverage of Suppliers of E.S. Services.

2. Bureau of Quality Assurance (BQA) DHEW, E.S.R.D. Program Guideline, Chapter 301, Introduction to Medical Review.

3. Draft Specific Criteria for Hemodialysis Services from Doctor Paul Doolan.

4. Inter-Office Correspondence from Dr. John T. Maher, Professor of Medicine, Director, Division of Nephrology U Conn Health Center to Doctor Paul Doolan, St. Mary's Hospital Quality of Care Committee dated 3/14/77.

5. Hemodialysis Blood Studies, AV Fistula Site Preparations, YNHH Care of AV Shunt, Special Blood Orders.
**Patient Introduction to Hemodialysis Unit, Hepatitis Screening of Patients and Tight Heparin Control Protocols from YNHH given 12/77.

6. Inter-Office Communication from Ms. Jenny Kitzen, Social Worker on Dialysis YNHH to Dr. Paul Doolan dated 4/11/77 RE Nephrology S.W. of Connecticut Optimal Guidelines of Practice also included Nephrology Dieticians of Conn. Optimal Guidelines for Practice.

7. Inter-Office Correspondence, Frederic O. Finkelstein to Doctor Paul Doolan RE Quality of Care, 3/30/77.

8. CHA Memorandum to Chief Executive Officers of CHA Member Institutions with E.S.R.D. Programs from Vincent A. Prota, Vice President, Planning RE DHEW Suggestions on Integration of E.S.R.D. M.R.B.'s with P.S.R.O. Review Plans, 6/22/77.

9. NCC #27 Response to the California Regional Medical Program Project Report to Ray A. Crystal, E.S.R.D. Program Director.

10. Inter-Office Correspondence, Alan S. Kliger, Assistant Professor of Medicine to Nelson Gelfman, M.D., Interim Chairman, NCC E.S.R.D. Program RE California.

11. Inter-Office Correspondence, Ms. Margaret Dunnington, Conn. Hemodialysis Registry Info. Coordinator to Nelson Gelfman, M.D. RE California Audit Project, 30 Boulder Hill Road, Ridgefield, CT 06877.

12. Valving Lives: The Policy Debate on Patient Care Financing for Victims of E.S.R.D., by Richard A. Rettig, Duke University Conference on Valving Lives, March 11, 13, 1976.

13. Implementation of the E.S.R.D. Program: A Unified Pattern of Subsidizing and Regulating the Delivery of Medical Services, by Richard A. Rettig, Annual Meeting American Political Scientist Association, San Francisco, California, September 2, 5, 1975.

14. Background Paper for November 19, 20, 1976, Conference: "Health Care Technology and Quality of Care," Lessons Learned from the E.S.R.D. Experience by Richard A. Rettig, Ph.D.

15. Medical Care, July 1977, Vol. XV, No. 7., The E.S.R.D. Networks: An Attempt Through Fed. Reg. to Regionalize Health Care Delivery, Lynda Diane Baydin, M.D.

16. Results of the Rx of E.S.R.D. Failure in a Defined Geographic Area, Sharon Banney, Et.al.

17. Institute of Medicine; Assessing Quality in Health Care and An Evaluation, Publication 76-94. National Academcy of Science, November 1977.

18. Williamson, John, W., M.D., Formulating Priorities for Quality Assurance Activity Description of a Method and its Systematic Application. JAMA - Special Communications, Feb. 13, 1978, Volume #239, #7, pp. 631-637.

19. A Self Instructional Guide Orientation to Public Law, 93-641; Adopted from a Guide Compiled by Dr. Grace Edison for the Bluegrass Regional Health Planning Council, Kentucky.

20. N.L. Tilney, Et.al., Treatment of Chronic Renal Failure by Transplantation and Dialysis. Two Decades of Cooperation, Annal Surgery, August 1975, Volume 182, #2.

21. The Tenth Report of the Human Renal Transplant Registry: JAMA, 221:1495, 1973.

22. Cutler, S. J. and Ederer, F.: Maximum Utilization of the Life Table Method in Analyzing Survival. J. Chronic Disease, 8:699, 1958.

23. Stengel, K.H., Whitsell, J.C., Stubenbord, W.T., Et.al.: Kidney Transplantation, Improvement in Patient and Graft Survival Annal Surgery, 180:29, 1974.

24. Conn, Rex, B., M.D., Clinical Laboratories: Profit Center Production Industry or Patient Care Resource? NEJM, Vol. 298, #8, pp. 422-427, February 23, 1978.

25. National Health Expenditure, Fiscal Year 1976. Social Security Bulletin 40:3, 1977.

26. Socioeconomic Issues of Health Center for Health Services Research and Development, Chicago, American Medical Association, 1975-76 Edition.

27. The 12th Report - Renal Transplant Registry, JAMA, August 18, 1975, Vol. 233, #7.

28. Management of the Patient with E.S.R.D. Proceedings of a Symposium at YUSM, 3/19/75, Sponsored by Kidney Foundation CT. Inc. Anemia of Renal Failure, Hendler, Erenesto, p. 37. Finkelstein Psychological Adoption of the Chronic Dialysis Patient., p. 33.

29. Levy, N.B.: Sexual Adjustment to Maintenance Dialysis and Renal Transplantation a National Survey by Questionnaire, T.A. SATO, 19, 238-193, 1973.

30. Friedman, Elia, A., M.D., Et.al.: Progmatic Realities in Uremia Therapy, NEJM, Special Articles, Vol. 298, #7, 2/16/78, pp. 368-371.

31. Stange, Paul, V., Et.al.: Predicting Treatment Costs and Life Expectancy for End Stage Renal Disease, NEJM, Special Articles, Vol. 298, #7, pp. 372-378, 12/16/78.

32. Kessner, David, M., M.D.: Quality Assessment Assurance, Early Signs of Cognitive Dissonance, 1 Ibid., p. 381.

33. The 13th Report of the Human Renal Transplant Registry, Transplant Proceedings JAMA 9:9-26, 1977.

34. Blagg, C.R.: Incidence and Prevalence of Home Dialysis, T. Dialysis, 1:475-493, 1977.

35. Cummings, N.B.: Research in Kidney and Urinary Tract Diseases Data Book for Fiscal 1976, Bethson Maryland, NIH, 1977.

36. Brook, R.H., Arey, A.D., Et.al.: Quality of Medical Care Assessment Using Outcome Measures, An overview of the Method (R 2021/1-HEW). Santa Monica, California, Rand Corporation, 1976.

37. Stranova, T.J.: Chronic Hemodialysis Patients in CT., Connecticut Medicine, July, 1974.

38. Pearson, D.A., Characteristics of Connecticut Patients Receiving Services for End Stage Uremia. U.S. Public Health Reports, Vol. 90, No. 5, pp. 441-448, 1975.

39. Lewis, E.J., Et.al.: Survival Data for Patients Undergoing Chronic Intermittent Hemodialysis. Ann. Internal Medicine, 70:311-315, February 1969.

figuras 1

Table [illegible] Estimated Renal Transplantations Performed in the United States[4]

Yr	No of Transplants*
1970	1,460
1971	2,209
1972	2,852
1973	3,017
1974	3,190
1975	3,730
1976	3,504

*Cadaver + living donor.

(a)

Table 3. Patients on Dialysis in the United States According to Mode of Therapy.*

Yr	Peritoneal Dialyses		Facilities Hemodialyses		Home Hemodialyses		Totals
	no	%	no.	%	no	%	
1970	63	2.6	1,549	63.1	844	34.4	2,456
1971	78	2.2	2,043	58.7	1,361	39.1	3,482
1972	96	1.9	2,933	58.3	2,001	39.8	5,030
1973	123	1.6	4,703	62.5	2,703	35.9	7,529
1974	211	2.0	6,780	65.2	3,402	32.7	10,393
1975	304	2.2	9,488	69.7	3,814	28.0	13,606
1976	378	2.2	12,775	74.1	4,076	23.7	17,229

*Abstracted from final report of National Dialysis Registry.[3]

(b)

ent Survival of Patient and Graft Two Years after Renal Transplantation.*

Cadaver Donors		Sibling Donors		Parent Donors	
Patient	Graft	Patient	Graft	Patient	Graft
51.5	38.8	82.4	74.4	75.4	67.1
58.5	46.8	78.6	72.1	72.2	62.3
62.5	47.1	83.3	77.2	81.6	69.6
62.7	45.9	82.0	69.7	82.1	67.4
63.7	43.8	85.5	72.9	81.5	64.7
65.4	41.1	84.6	70.2	81.1	62.2

t of Human Renal Transplant Registry.[4]

(c)

Table 4. Survival of Patients on Hemodialysis Begun in 1972 to 1974 Treated at Home or Facility.*

Place of Treatment	No. of Patients	Mean Age (Yr)	% Living at 1 Yr	% Living at 2 Yr
Facility	17,991	43.0	85.5	77.0
Home	9,013	43.7	93.9	86.2

*Abstracted from final report of National Dialysis Registry.[3]

(d)

(e)

Table 1. End-of-Year Survival Rates According to Method of Treatment.

Method	Yr									
	1*	2	3	4	5	6	7	8	9	10
Facility dialysis†	0.901	0.835	0.760	0.684	0.616	0.551	0.499	0.449	0.404	0.364
Home dialysis†	0.939	0.862	0.786	0.707	0.637	0.573	0.516	0.464	0.418	0.376
1st cadaveric transplant:										
Low assumption‡:										
Patient	0.723	0.654	0.614	0.550	0.510	0.459	0.413	0.372	0.335	0.301
Graft	0.463	0.411	0.400	0.371	0.346	0.311	0.280	0.252	0.227	0.204
High assumption§:										
Patient	0.810	0.740	0.700	0.640	0.600	0.540	0.485	0.435	0.390	0.350
Graft	0.500	0.455	0.425	0.390	0.360	0.325	0.290	0.260	0.235	0.210
2d cadaveric transplant¶:										
Patient	0.660	0.580	0.550	0.530	0.510	0.460	0.410	0.370	0.330	0.300
Graft	0.500	0.420	0.380	0.330	0.320	0.290	0.280	0.260	0.230	0.210

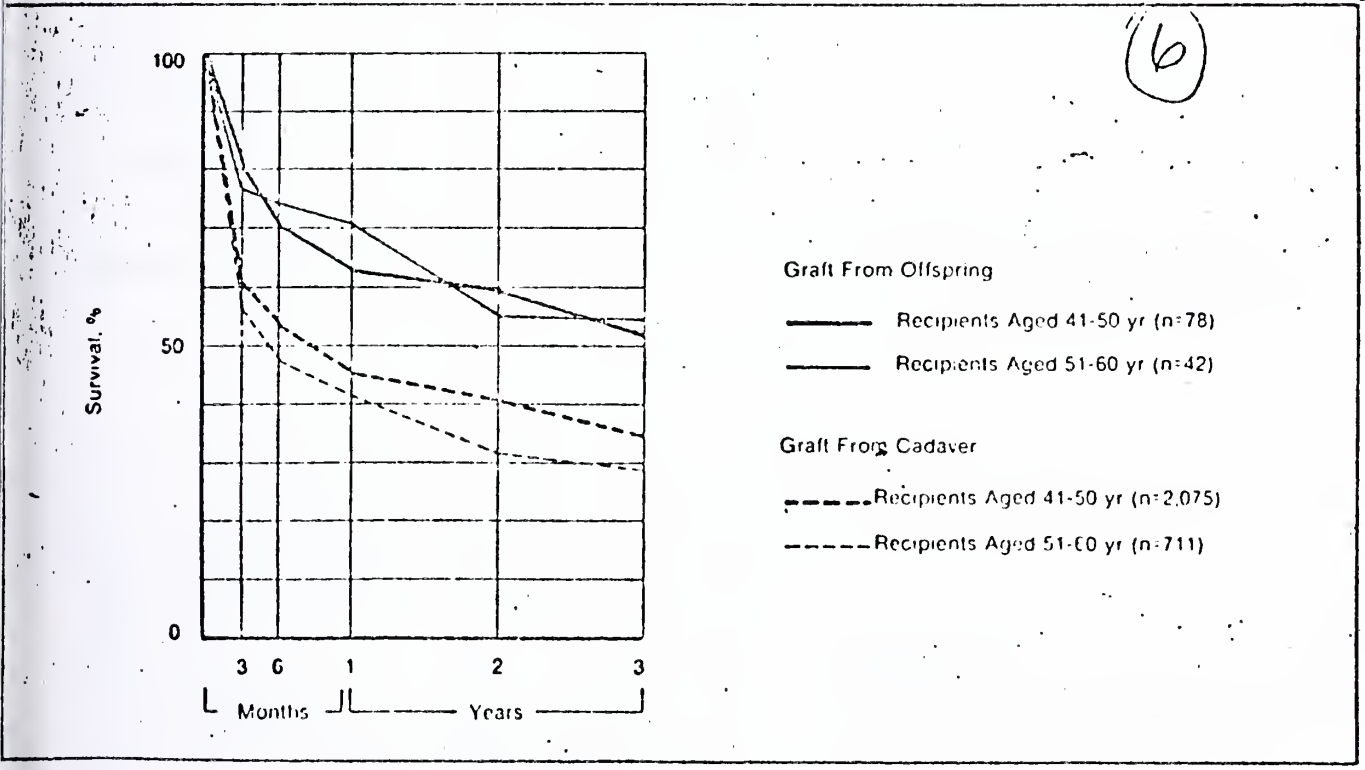
*Owing to "renormalizing" the 1st-yr facility-dialysis figures represent the 2d-yr experience but the 1st-yr experience for other treatment methods.

†Source, National Dialysis Registry Final Report (1976)[3] for yr 1-3; 10% mortality rate applied for yr 4-10.

Figure

II

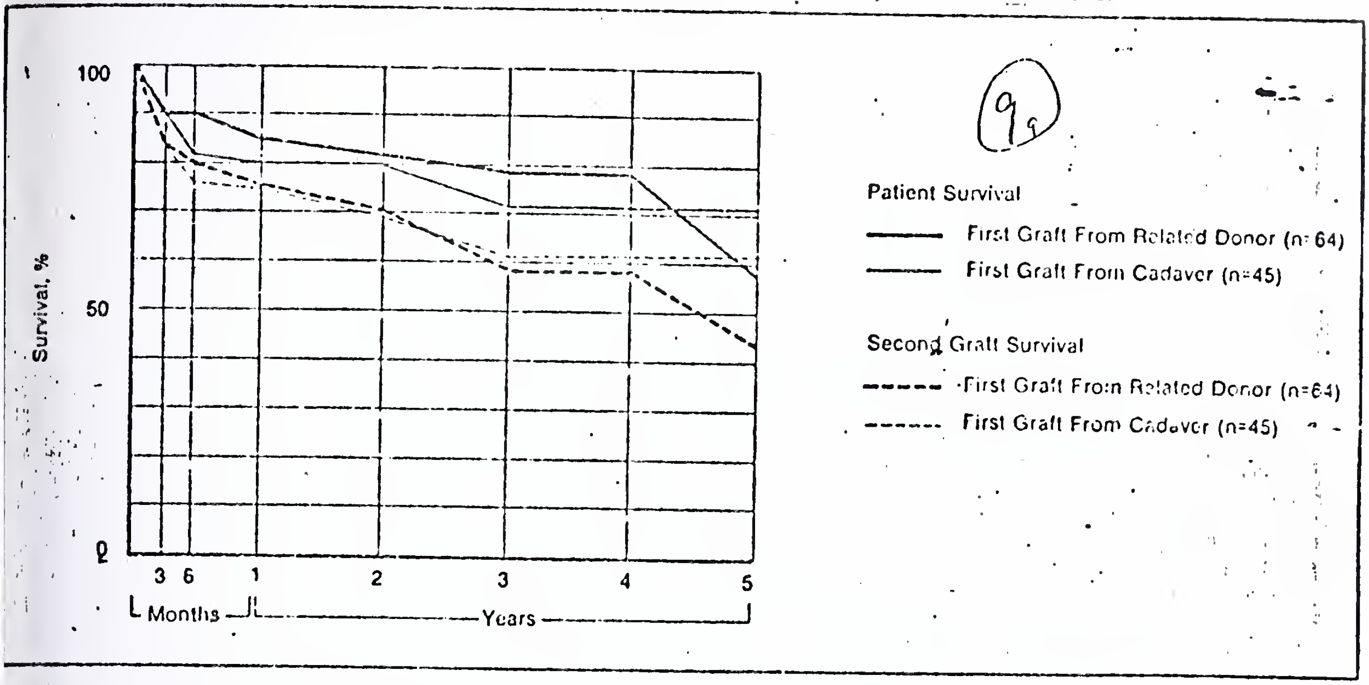
Fig 3.—Functional survival of grafts from offspring and cadavers in recipients aged 41 to 60 years.



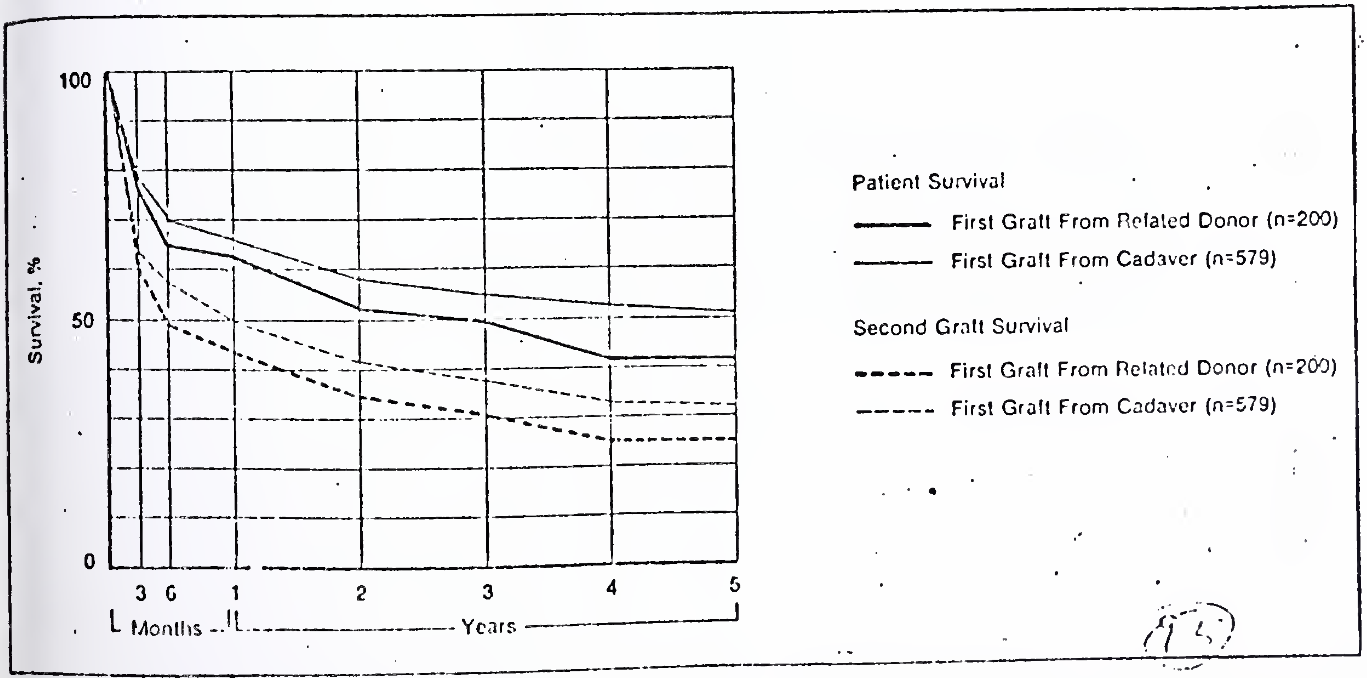
(6)

III

Fig 1.—Survival of second graft and patient receiving second graft from related donor



9a



9b

Fig 2.—Survival of second graft and patient receiving second graft from cadaver.

IV

(8)

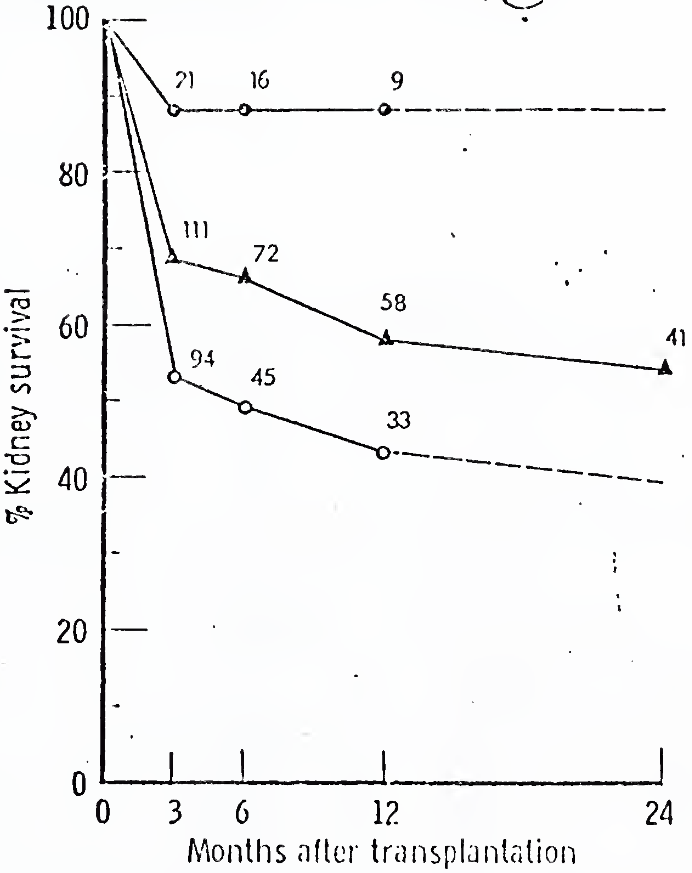


FIG. 3. Predicted kidney survival for HL-A identical siblings ○, non HL-A identical related living donors △ and cadaver donors ○. The dotted lines indicate trends with small number of patients at risk.

Figure V

Distribution of Pts by Type of Treatment

(a)

All modalities	353	100 0	212	100.0	[illegible]	
In-center[1]	294	83.3	165	77.8	98	[illegible]
Home dialysis[2]	58	16.4	46	21.7	5	4 9
Limited care dialysis[3]	1	.3	1	.5		

[1] Treatment in a center where therapy is provided by trained staff who are completely responsible for administering and monitoring the patient's dialysis.

[2] Performed by the patient usually assisted by a family member, after appropriate training. During the training period, patients receive in-center dialysis treatment.

[3] See description in Definitions section.

(b)

Table 7. Distribution of patients by ethnicity, Connecticut, 1966–72

Ethnicity	Total patients		Active patients		Deceased patients	
	Number	Percent	Number	Percent	Number	Percent
Total	353	100.0	212	100.0	103	100 0
White	288	81.0	166	78.0	88	83 0
Puerto Rican	7	2.0	3	1.0	2	2.0
Nonwhite	87	19.0	48	22.0	17	17.0
Black	65	18.4	44	21.0		
Oriental	1	.3	1	.5		
American Indian	1	.3	1	.5		

NOTE: Percents may not total because of rounding.

Table 3. Distribution of treatment units and patients and treatment units per million population, by health service area, Connecticut, 1972

(c)

Health service area	Treatment units			Patients			
				Residing in HSA		Received care in HSA	
	Number	Percent	Per million population[1]	Number	Percent	Number	Percent
All areas	64	100.0	21	[2]209	100.0	[3]212	100.0
Greater Bridgeport	12	18.7	38	32	15.3	49	23.1
Housatonic Valley	5	7.8	35	13	6.2	13	6.1
South Central	21	32.8	38	49	23.4	58	27.4
Central Naugatuck Valley	6	9.4	27	15	7.2	15	7.1
Capitol	16	25.0	18	60	28.7	69	32 5
Southwestern	4	6.2	12	16	7.7	8	3.8
Southeastern				14	6.7		
Mid-State				5	2.4		
Northeastern				4	1.9		
Northwestern				1	.5		

[1] Based on 1970 U.S. Census data. [2] Connecticut residents only. [3] Includes 3 nonresidents.

NOTE: Percents may not total 100 because of rounding.

(d)

Table 4. Summary of chronic hemodialysis programs, Connecticut, as of November 30, 1972

Health service area and program	Number of treatment units	Full-time equivalent staffing[1]	Average hours per week program operated
Greater Bridgeport:			
Bridgeport Hospital	7	6.4	88
St. Vincent's Hospital	5	4.7	80
Housatonic Valley:			
Danbury Hospital	5	5.1	42–48
South Central:			
Yale-New Haven Hospital	4	8.6	64–80
St. Raphael's Hospital	3	3.1	[2]40
VA Hospital-West Haven	14	18.8	66
Central Naugatuck Valley:			
Waterbury Hospital	3	2.9	69
St. Mary's Hospital	3	3.3	54
Capitol:			
Hartford Hospital	10	0	112
St. Francis Hospital	4	4.2	70
McLean Home	2	1.4	42–48

Southwestern:
Norwalk Hospital
4 1.7 40

Figure VI

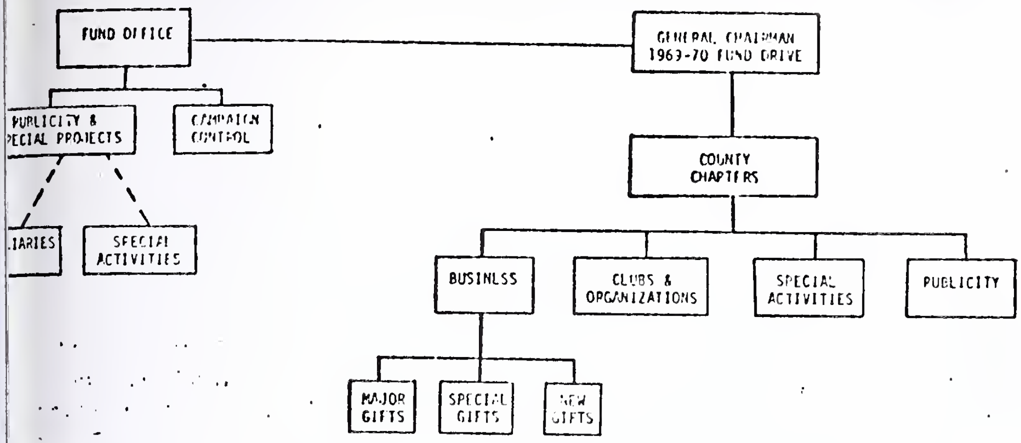


Figure 1.

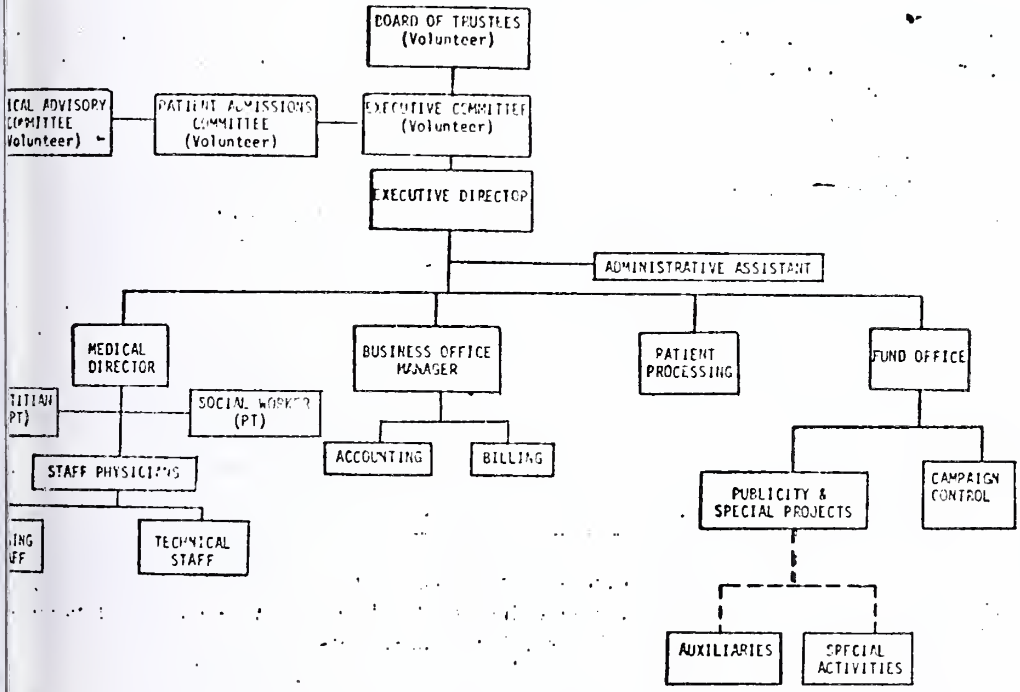


Figure 2.

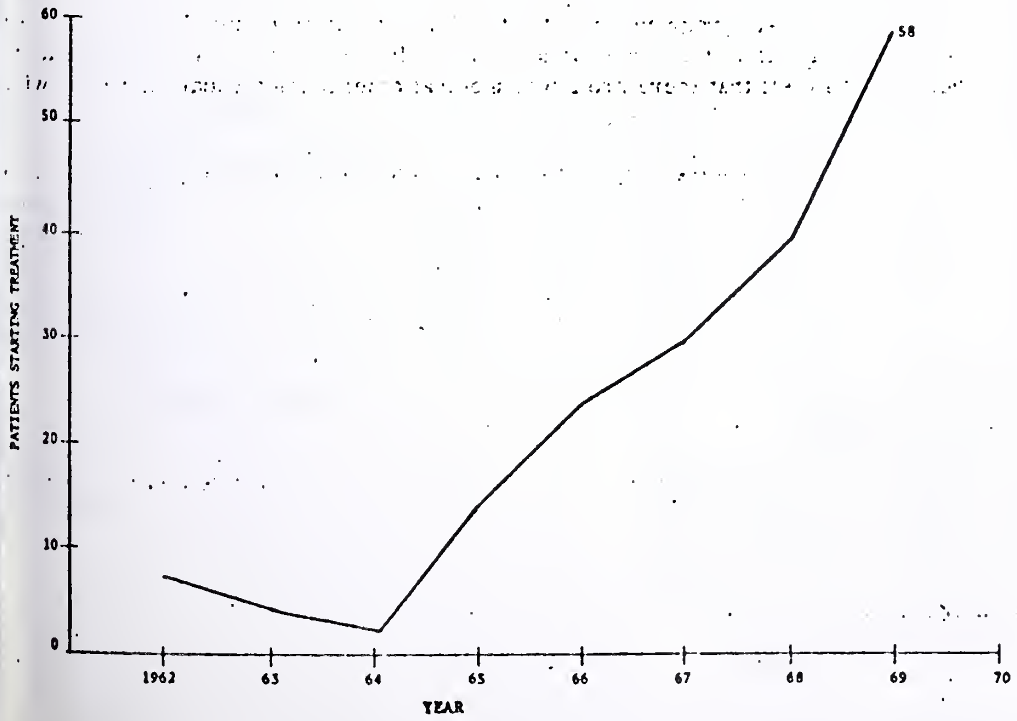


Figure 3. Annual Population Growth.

[illegible]

ras, J., et al. Eight years' experience with a dialysis center Figure VII

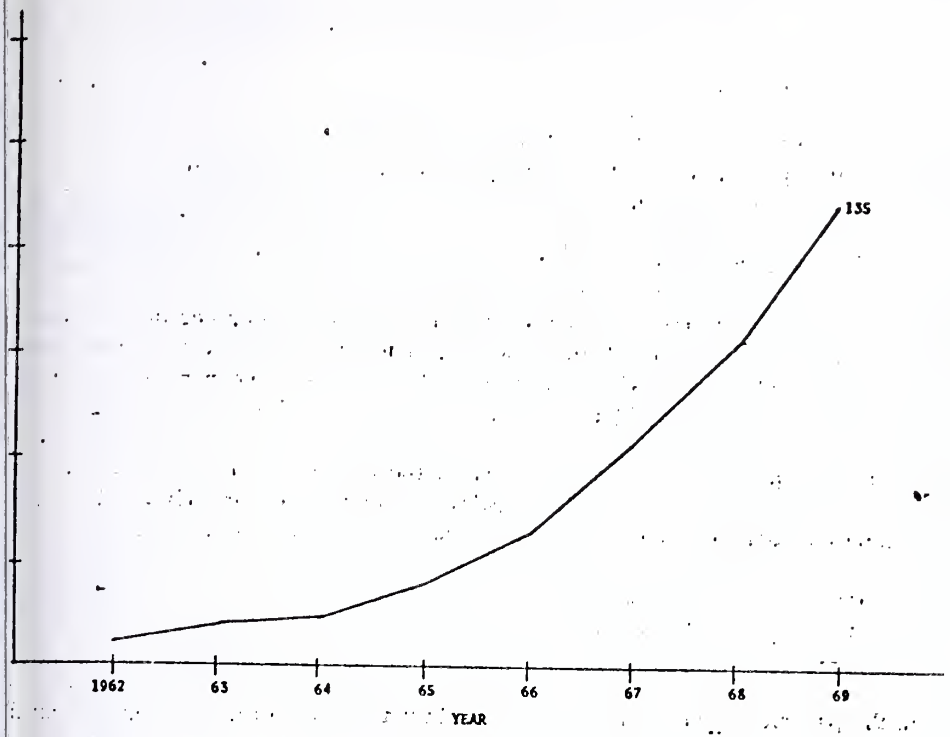


Figure 4. Cumulative Patient Population.

③

TABLE II

NORTHWEST KIDNEY CENTER PATIENT CENSUS

DECEMBER 31, 1969

HOME HEMODIALYSIS	104
HOME PERITONEAL DIALYSIS	4
TRANSPLANTS	12
HOME TRAINING	8
CENTER	7
	135

TABLE III

TOTAL MEDICAL PERSONNEL

MEDICAL DIRECTOR	1
STAFF PHYSICIANS	1.5
NURSES	8
TECHNICIANS	8
DIETITIAN (PT)	1
SOCIAL WORKER (PT)	1

HOME TRAINING PERSONNEL

PHYSICIANS	2
NURSES	4
TECHNICIANS	4

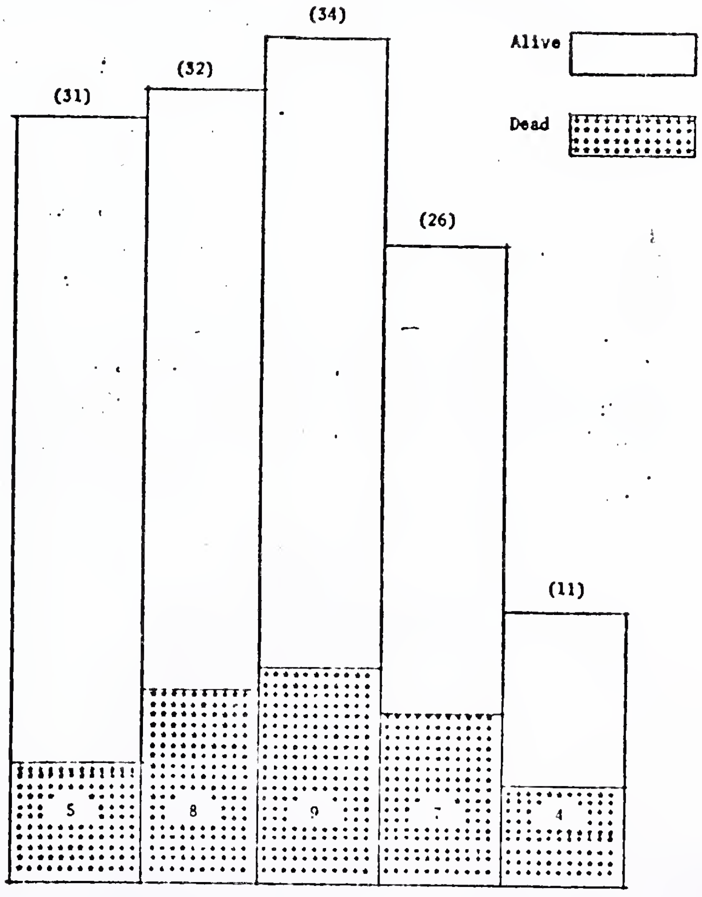


Figure 5. Patient Age Distribution (age at start of treatment).

Figure VIII

TABLE IV

1969 BACK-UP DIALYSIS EXPERIENCE

AVERAGE NUMBER PATIENTS HOME	82
TOTAL NUMBER BACK-UP DIALYSES	531
AVERAGE NUMBER BACK-UP DIALYSES/PT./YR.	6.5
MAXIMUM NUMBER BACK-UP DIALYSES PER 24 HOUR PERIOD	6
NUMBER BACK-UP BEDS FOR 82 PATIENTS	4
PATIENT:BACK-UP BED	20:1

TABLE V

REHABILITATION RESULTS OF HOME DIALYSIS PATIENTS

TOTAL	73%
PARTIAL	24%
NONE	3%

④

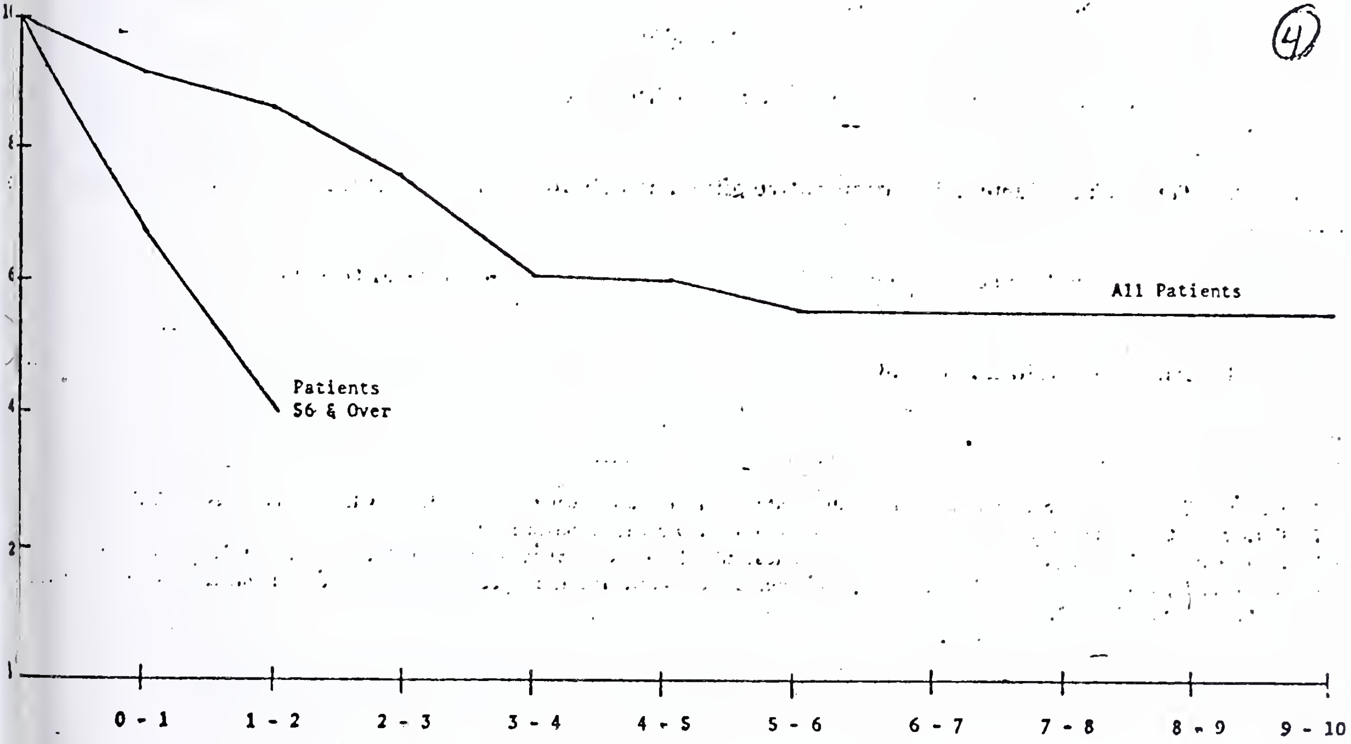


Figure 6. Dialysis Survival Curve (years of treatment).

TABLE VI

DEATH ETIOLOGY

CEREBRAL	8
CARDIAC	6
CALCIUM	3
ACCIDENTAL	3
HEPATIC	2
SUICIDE	2
MISCELLANEOUS	10

TABLE VII

TEN MISCELLANEOUS DEATHS

HYPERKALEMIA	2
PERICARDIAL TAMPONADE	1
COLLAGEN DISEASE	1
NEUROMUSCULAR BLOCKADE	1
CANCER	1
UNKNOWN	4

[illegible] Report of the Human Renal Transplant Registry [illegible]

¶Source, Twelfth Report of the Human Renal Transplant Registry (1975)** for yr 1-5, 10% mortality rate applied for yr 6-10. For the low assumption, yr 1-5, rates included in the Twelfth Report of the Human Renal Transplant Registry (1975)**, 10% mortality rate applied for yr 6-10. For the high assumption, 1st transplant survival rates were used.

Figure IX

Table 2. Estimated Annual Patient Costs According to Method of Treatment (Current Dollars) *

Method	Yr 1	Yr 2	Yr 3	Yr 4-10
Facility dialysis	24,500	24,500	24,500	24,500
Home dialysis†	17,000	15,400	15,400	15,400
Cadaveric transplantation‡:				
1st yr costs	25,000	—	—	—
Follow-up costs:				
For patients with successful grafts:				
Stable success:				
% of surviving patients	—	75%	92%	92%
Follow-up costs	§	3,000	2,000	1,500
Unstable success:				
% of surviving patients	—	25%	8%	8%
Follow-up costs	§	9,000	9,000	9,000
Rejection costs¶	§	10,000	10,000	10,000
Dialysis costs:				
For patients surviving & returning to:				
Facility dialysis	24,500	24,500	24,500	24,500
Home dialysis	15,400	15,400	15,400	15,400

*Source, Internal Management Reports assessing the National Cost and Charge Experience (Chronic Renal Disease Branch, Medicare Bureau, Health Care Financing Administration).

†Costs of home-dialysis equipment & supplies reflect 1976 catalog prices of major suppliers. Costs of those who assist patients with the operation of home-dialysis equipment excluded.

‡Applicable to 1st & 2d transplants (1st-yr costs for 2d transplants are estimated at $20,000)

§Included in 1st-yr costs.

¶1-time additional costs in yr of rejection incurred by all patients with rejection of transplants.

Table 4. Cumulative Discounted 10-Year Costs and counted Life-Years Associated with Three Treatment Tr tion Options (1000 Patients Shifting Annually).

Option	Life-Yr	Co ($ Mi
Facility dialysis to home dialysis:		
Facility dialysis*	25,979	$71
With transition to home dialysis	26,790	477
Facility dialysis to cadaveric transplantation:		
Facility dialysis*	25,979	$717
With transition to cadaveric transplantation (low assumption)	21,478	387
With transition to cadaveric transplantation (high assumption)	24,177	438
Home dialysis to cadaveric transplantation:		
Home dialysis*	26,790	$477
With transition to cadaveric transplantation (low assumption)	21,478	334
With transition to cadaveric transplantation (high assumption)	24,177	374.

*Without transition

Table 3. Discounted Life-Years and Costs for 1000-Patient Cohorts According to Method of Treatment ($ Millions).

Method	Yr										Cohort Totals
	1*	2	3	4	5	6	7	8	9	10	
Facility dialysis:											
Life-yr	889	758	651	551	463	390	328	276	232	195	4,733
Costs ($)	22.19	19.29	16.89	14.55	12.48	10.69	9.18	7.86	6.74	5.78	125.65
Home dialysis:											
Life-yr	907	787	673	570	479	403	339	285	240	202	4,885
Costs ($)	15.71	12.59	10.96	9.46	8.11	6.95	5.96	5.11	4.38	3.75	82.98
Cadaveric transplantation (low assumption):											
Life-yr	806	595	505	439	376	324	274	230	194	163	3,906
Costs (including post-rejection facility dialysis) ($)	27.42	6.99	4.83	4.09	3.51	3.16	2.69	2.31	1.95	1.67	58.62
Costs (including post-rejection home dialysis) ($)	26.63	5.49	3.47	2.96	2.55	2.30	1.96	2.70	1.42	1.23	50.71
Cadaveric transplantation (high assumption):											
Life-yr	847	676	582	510	442	378	318	267	225	190	4,435
Costs (including post-rejection facility dialysis) ($)	28.12	8.13	6.25	5.43	4.80	4.20	3.60	3.13	2.66	2.30	68.62
Costs (including post-rejection home dialysis) ($)	27.18	6.29	4.47	3.83	3.41	3.01	2.56	2.22	1.90	1.64	56.51

*Owing to "renormalizing" the 1st-year facility-dialysis figures represent the 2d-yr experience for facility-dialysis treatment but the 1st-yr experience for other treatment methods.

federal register

THURSDAY, JUNE 3, 1976

THE NATIONAL ARCHIVES OF THE UNITED STATES 1934

PART II:

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Social Security Administration

■

RENAL DISEASE

Implementation of Coverage of Suppliers of End Stage Services

Title 20—Employees' Benefits

CHAPTER III—SOCIAL SECURITY ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[Regulations No. 5, further Amended]

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services

The amendments to the regulations set forth below are adopted in final form by the Commissioner of Social Security with the approval of the Secretary of Health, Education, and Welfare. These amendments are intended to further implement Section 2991 of the Social Security Amendments of 1972 (P.L. 92-603), which extends Medicare protection to any individual who has end-stage renal disease requiring dialysis or transplantation, provided that such individual: (1) is fully or currently insured, or entitled to monthly benefits under Title II of the Social Security Act; or (2) is the spouse or dependent child of an individual so insured or entitled to such monthly benefits.

On July 1, 1975, there was published in the FEDERAL REGISTER (40 FR 27782) a Notice of Proposed Rule Making with proposed amendments to regulations relating to: (a) the conditions for coverage which suppliers of ESRD services must meet to qualify for Medicare reimbursement; (b) the certification procedures for such suppliers; (c) the provision of a minimal utilization rate for covered procedures; (d) the designation of ESRD network areas; (e) the establishment of Network Coordinating Councils, and (f) the provision of Medical Review Board to screen the appropriateness of patients for the proposed treatment procedures, in order to implement Section 2991 of the Social Security Amendments of 1972 (P.L. 92-603).

Interested parties were given the opportunity to submit data, views, or arguments on the proposed amendments within 60 days of the July 1, 1975, notice of proposed rulemaking. Comments were received from many sources (including representatives of national, State and local organizations) concerned with ESRD care of patients. Approximately 45 letters were received, many of which contained comments on various portions of the proposed regulations so that the total number of comments approximated 15). Although a large number of comments were received after the September 1, 1975 deadline, each comment received has been carefully considered. The largest number of comments were in the areas of the definitions concerning ESRD facilities and personnel, network areas and organizations (network coordinating council and medical review board), and minimal utilization rates. A lesser number of comments were related to histocompatibility testing, and the health and safety requirements for facilities.

For purposes of organization, the discussion of the comments and the actions taken follows the sequence of the sections of the regulations.

Section 226(g) of the Social Security Act (the Act) authorizes the Secretary to limit Medicare reimbursement for kidney transplant and dialysis services to facilities meeting such requirements as he may by regulation prescribe. Section 226(g) also provides that such regulations must include requirements for a minimal utilization rate for covered procedures and for a medical review board to screen the appropriateness of patients for the proposed treatment procedures.

The following amendments to the regulations specify the health and safety requirements that facilities furnishing ESRD services must meet to qualify for Medicare reimbursement. In addition, the amendments require that these facilities be organized into coordinated systems ("networks") for the delivery of ESRD care.

The ESRD program became effective July 1, 1973, and since then has operated under interim regulations published in the FEDERAL REGISTER of June 29, 1973 (38 FR 17210). The interim regulations provide for reimbursement to those facilities which were furnishing ESRD care on or before June 1, 1973, and describe criteria for allowing reimbursement to additional or expanded ESRD facilities during the interim period. (To give the public a formal opportunity to participate in the development of the criteria used in granting requests for exceptions to the limitation on participation during the interim period, the interim regulations were republished in the FEDERAL REGISTER of April 22, 1975 (40 FR 17746)) after. Notice of Proposed Rule Making. The interim regulations, as published and republished are being superseded by these "long-term" amendments to the regulations. The interim regulations explained that recognition of a facility on an interim basis was no assurance that it would be approved on a continuing basis for reimbursement under the "long-term" program. Facilities not qualifying under the "long-term" regulations will be phased out in a manner that will minimize any disruption of services to ESRD patients.

The policies for the ESRD program which are incorporated in these amendments are based on the operating experience of the program since publication of the interim regulations in June 1973, as well as on extensive communications with professionals and other persons knowledgeable in the areas of nephrology and transplant surgery.

These amendments are intended to accomplish the following objectives:

(1) To assist beneficiaries who have been diagnosed as having ESRD to receive the care they need;

(2) To encourage proper distribution and effective utilization of ESRD treatment resources while maintaining or improving the quality of care; and,

(3) To provide the flexibility necessary for the efficient delivery of appropriate care by physicians and facilities.

The broad array of professional skills and facilities involved in the treatment of persons with ESRD indicates the need for a system to promote effective coordination. Accordingly, these final regulations require ESRD treatment facilities to join together into groups called "networks".

During the past decade, programs conducted by agencies of the Public Health Service and the States have demonstrated that integration of hospitals and other health facilities into organized networks is the most effective way to deliver ESRD care. An organized network tends to assure coordinated patient referral as well as access to resources. It also permits the concentration of equipment and specially trained personnel in centers where they can be used efficiently to treat large numbers of patients. This approach has been advocated by committees of national voluntary health organizations.

The population base of each network should be large enough to permit the delivery of a full range of ESRD diagnostic and therapeutic services needed by all patients within the network area. Accordingly, 26 of the network areas designated in the Appendix to the Subpart U serve a minimum population base of 3.5 million, (while an additional six network areas serve a smaller population base as this minimum would not be feasible). In order to accommodate patient choice, and to allow for sufficient peer review within the network, each network will be required to have at least two transplant centers whenever feasible.

Pts Choice

The network concept will be found in existing patterns for referral of patients to treatment facilities, these existing referral patterns in effect constituting informal networks. Insofar as feasible, network designations conform with these referral patterns. Alhough the designation of network areas is made by the Secretary, the structure and the administration of each network will be the responsibility of the representatives of its component ESRD facilities.

These final regulations require that in order to qualify for reimbursement, an ESRD facility must be a member of a network. The network must organize itself through the establishment of a Network Coordinating Council, with representation from all ESRD facilities in the network. The network and its Council will perform a unique role as liaison between the Federal Government and available community resources, with the Council supplying to the Secretary information which the Secretary may use to make determinations. The Council will also make recommendations to member facilities as needed to achieve the objectives of the network. In addition, each network, through its Council, will establish a Medical Review Board to review the appropriateness of ESRD patient care and service.

mandatory Network member

An essential element in the ESRD program is a medical information system. All ESRD facilities participating in the program will be required to supply data to this system. When the medical information pertains to individual patients, it will be treated as confidential and will not be disclosed except as authorized by Department regulations on confidentiality and disclosure (see 45 CFR Parts

5 and 5b and 20 CFR Parts 401 and 422 (Subpart E)).

For participation in the ESRD program, a facility must also meet the minimal utilization rates for covered procedures published in these final regulations. These rates apply to transplantation and dialysis, and may be modified by future amendments to the regulations. A facility which is not in compliance with the applicable minimal utilization rates may be conditionally approved for a limited period to allow it time for attaining compliance. These final regulations also provide for exceptions to the minimum utilization rates to be granted to a dialysis facility in unusual situations if it can be shown that nonparticipation in the ESRD program would be detrimental to the achievement of program objectives.

Through a Memorandum of Understanding reflecting agreement reached between the Department of Health, Education, and Welfare and the Veterans Administration, specified Veterans Administration Hospitals can qualify for participation in the ESRD program. These specified Veterans Administration Hospitals, when found to meet Title XVIII requirements, will be part of a network and will be represented on its Council. They will also be required to comply with the ESRD regulations described herein with respect to the care they furnish to Medicare patients. Similarly, other Federal facilities may participate in the ESRD program provided that they meet the requirements of these regulations.

To conform other pertinent regulations with Subpart U and ESRD program requirements, these final regulations amend Subpart M (Conditions for Coverage of Services of Independent Laboratories (39 FR 33690)) to include requirements for an independent laboratory performing histocompatability testing; Subpart S (Certification Procedure for Providers and Suppliers of Services); and Subpart J (Conditions of Participation; Hospitals). Subpart O (Providers of Services, Emergency Service Hospitals, Independent Laboratories, and Suppliers of Portable X-ray Services, Determinations and Appeal Procedures) has elsewhere been amended to reflect implementation of the ESRD program. 41 FR 8481 (February 27, 1976).

General Comments

Many of the comments were of a general nature. For example, while many comments suggested changes in network area designations and the composition and functions of the network organizations, the comments contained substantial support for the concept of organized ESRD networks to promote coordinated patient referral and access to the full range of resources.

A number of comments suggested that there is a need for clarification of the way in which these regulations apply to the various types of facilities which furnish ESRD services. For example, several comments indicated concern that the regulations apply in detail to facilities furnishing dialysis services but apply only minimally to renal transplantation facilities. Other comments indicated concern that the proposed regulations would establish requirements which were nearly duplicative of the existing requirements for hospitals under the Medicare program. The proposed regulations recognized the fact that renal transplantation centers and renal dialysis centers are hospitals participating as providers in the Medicare program. Also participating skilled nursing facilities may wish to be approved as renal dialysis facilities, while hospital laboratory departments and independent laboratories may wish to furnish the laboratory specialty of histocompatiblity testing. However, providers or suppliers of services currently participating in the Medicare program must also meet the conditions for coverage contained in the these amendments to regulations in order to become approved as suppliers of ESRD services and in order to become approved to furnish the laboratory specialty of histocompatibility testing.

Section 226(g) of the Act authorizes the Secretary to limit Medicare reimbursement for kidney transplant and dialysis services to facilities meeting such requirements as he may by regulation prescribe. These amendments to the Medicare regulations provide the requirements which facilities must meet in order for their services to be covered under the ESRD program. Hospitals, to participate in the Medicare program, must be in compliance with the conditions of participation which are listed in Subpart J of the Medicare regulations. Examples of the conditions of participation in Subpart J are: Governing Body, Physical Environment, Medical Record Department, etc. The Conditions for Coverage of Suppliers of ESRD Services listed in Subpart U of these amendments similarly contain: Governing Body and Management, Physical Environment, Medical Records. Hospital compliance with the requirements for reimbursement of ESRD services will be considered within the context of the furnishing of ESRD services. For example, a Medicare approved hospital will have a functioning Governing Body; approval for reimbursement for ESRD will require (see section 405.2136) that in addition, there be documentation that the Governing Body receive and act on communications from the Medical Review Board of the ESRD network since other aspects will have been certified under the conditions of participation. Similarly, hopsitals accredited by the Joint Commission on Accreditation and by the American Osteopathic Association are deemed to meet the Medicare conditions of participation with the exception of utilization review, and institutional planning (Subpart J) and will also need to meet the requirements in Subpart U to be approved for reimbursement for ESRD services. Many other examples could be cited. Guidelines and instructions will be forthcoming to assist surveyors in relating these requirements to the furnishing of ESRD services.

Other writers commented that the proposed regulations were not consistent with one of the objectives of the ESRD program (Section 405.2101) in that very little flexibility was provided for in the requirements concerning ESRD facilities. In answer to these comments, the Department believes that although the regulations place certain requirements upon facilities, the manner in which the re-facilities, the manner in which the requirements may be fulfilled can vary. As an example, Renal Dialysis Facilities are required to periodically analyze and treat the water used in dialysis and to maintain records of test results. This provides the opportunity for standards for testing to change to be compatible with currently acceptable dialysis techniques. There is an important need to retain flexibility as an operating policy since the care of patients with ESRD can be expected to be subject to rapid changes. Interpretation of the regulations, as well as future amendments to the regulations, should not stifle acceptable and needed technological changes which may influence concepts of good ESRD patient care.

Many comments were received from patients presently undergoing treatment for ESRD; their major concerns were that the designated network areas would prevent patients from receiving care from facilities located in a network area other than the area in which the patient resides. It should be understood that network areas relate only to the location of facilities and not to the residence of patients; it is explicit in section 1802 of the Act and in section 405.2110 that patients may receive care at the facility of their choice. The regulations provide for the ESRD facilities within each designated area to organize to carry out review of ESRD patient care being furnished by facilities located in the network area and to plan to achieve appropriate access for all ESRD patients treated by the facilities in their area. Thus, while the network areas were drawn with reference to current patient flow and include all the modalities of ESRD care, a patient is not precluded from receiving care in a facility outside the network area in which he or she resides.

Comments on various sections of the proposed regulations pointed out apparent omission of needed items and suggested that these items be added to the regulations. For example, the proposed regulations prescribe that the Director of an ESRD dialysis facility be responsible for the training of nurses and technicians in dialysis techniques. Some who commented suggested that the Director be responsible for a training program for all of the staff. These final regulations require the Chief Executive Officer to be responsible for ensuring that all employees have an opportunity for continuing education and related development activities in addition to appropriate orientation to the facility and their work responsibilities upon employment.

It was felt in this example and in others, that the suggestions were addressed in other sections of the proposed regulations. However, to aid public understanding, greater effort has been made to cross-reference the revised regulations.

Several comments were received which lid not deal specifically with the pro- posed regulations but were general com- nents on provisions of the statute (P.L.)2-603) or on aspects of reimbursement olicy not addressed in these amend- nents to the regulations. The latter com- nents were not considered to be within he scope of review for suggested hanges in proposed regulations.

Comments on condition of participa- ion—complementary departments (sec- ion 405.1031). Comments received which ere relevant to this section are dis- ussed under general comments. This ection amends the regulations for hos- ital participation in the Medicare pro- ram to indicate that, if a participating spital provides ESRD services, reim- ursement for such services will not be ade unless the hospital also meets the nditions for Coverage in Subpart M d U of these regulations as appropri- e. Comments suggesting that a hospi- l which meets the Conditions for Par- ipation in the Medicare program ould be deemed to meet at least part the requirements of Subpart U have en rejected, since the body of ESRD gulations must apply to all ESRD fa- ities, regardless of location.

omments on histocompatibility test- (sections 405.1310, 405.1314, 405.1317, .2171Q. A small number of comments re received which suggested changes the proposed requirements for histo- npatibility testing. Most of these com- nts were from individuals who identi- themselves as directors of existing oratories which conducted histocom- ibility testing and pointed out several hnical inaccuracies in testing tech- ues which had been written into the posed regulations. One example of h an inaccuracy was the requirement t recipient and donor sera be cross- tched for preformed antibodies ereas the correct statement should e been that recipient serum and donor phocytes be crossmatched for pre- ned antibodies. These comments also nted out the inappropriateness of sifying histocompatibility testing er the existing clinical laboratory re- ements without identifying such test- as a separate entity.

hanges have been made which closely llel the recommendations. Histo- patibility testing is now defined in independent laboratory regulations tion 405.1317); specific qualification irements for the director or super- r are stated for a laboratory if the ratory performs tests in the specialty stocompatibility testing. In addition, requirements for quality control sys- are specifically identified for histo- patibility testing rather than grouped r immunohematology and serology the previous proposed regulations. ital laboratory departments which wish to be reimbursed under the ESRD program for histocompatibility testing must also satisfy these requirements.

Comments on the certification process (sections 405.1901 and 405.1912). Section 405.1901 has been changed to include cross-references to the sections which specify the requirements which a histocompatibility testing laboratory must meet. Suggestions were made that section 405.1912 be written in more detail to explain the special procedures involved in approval of ESRD facilities. In addition to changes made in section 405.1912, guidelines will be issued which will outline the details for ESRD facility approval. As published, section 405.2122 contained both substantive and procedural provisions relating to minimal utilization rate classifications. References to minimal utilization rates (discussed in greater detail below under the heading "Comments on minimal utilization rates") have been added to sections 405.1912 (b) through (e), in addition to simplification and clarification of the material now appearing in section 405.2122.

Comments on definitions (section 405.2102). This section received a large number of comments. Most of these comments indicated a need to consider changes in the definitions of types of services and facilities and of the types of qualifications of personnel in ESRD facilities.

A number of suggestions were made to restructure the definition of inpatient dialysis and chronic maintenance dialysis. It was suggested that a category of "Special Care Out-Patient Dialysis" be added to distinguish the usual routine chronic maintenance dialysis which might be carried out in an outpatient facility from the more specialized care required because of intercurrent complications or medical problems. Other comments suggested several variations now in use for defining dialysis by levels of care. In light of the difficulty encountered in arriving at universally accepted categories of levels of care it has been considered preferable to simplify the definition of dialysis and therefore avoid the resultant proliferation of standards for each level of care. Changes which have been made in the regulations in the interest of simplification were to delete the definitions of Limited Care Dialysis Facility, Self-Care Dialysis Facility and Self-Care Dialysis Training Facility and to substitute the definition of Dialysis Facility as a unit which is approved to furnish dialysis service(s) to ESRD patients. These services include chronic maintenance dialysis (at any level of patient involvement) and self-care dialysis training. There now are only two types of facilities defined primarily for dialysis; (1) the Renal Dialysis Facility and (2) Renal Dialysis Center. The definition of a Renal Dialysis Center has been slightly modified to explicitly state that the services include dialysis in a manner that makes a Center responsible for the care delivered to the hospitalized ESRD patient (i.e., furnished directly or under arrangement).

ESRD Services (section 405.2102(f)) have now been defined to better clarify the regulations with respect to types of ESRD services. Transplantation Service has been defined as suggested by several commenters to include not only the removal and implantation of kidneys but the supportive care which is furnished to the recipient and the living donor following implantation and removal. Dialysis Service (section 405.2102(f)(2)) is now defined under (1) Chronic Maintenance Dialysis, (2) Inpatient Dialysis, and (3) Self-Care Dialysis Training. The concept of self-care dialysis in a facility has been omitted from the definitions following comments that further investigation and discussion is needed before being introduced into regulations. To clarify Organ Procurement, the definition of an Organ Procurement Facility has been deleted and replaced by the definition of an Organ Procurement Agency (see item (q) in section 405.2102) which is defined as an organization which performs or assumes responsibility for all of the following services: (1) harvesting of donated kidneys, (2) preservation of donated kidneys, (3) transportation of donated kidneys, and (4) maintenance of a system to locate prospective recipients for harvested organs.

Transplant Service definition

Organ procurement (Agency)

The large number of comments on qualifications of personnel in ESRD facilities focused mainly on Dietitian (Qualified) and Social Worker (Qualified). The comments were nearly unanimous in the belief that at least one year of experience in clinical nutrition was necessary for assessing the nutritional dietetic needs of each patient, recommending therapeutic diets, counseling patients and their families on prescribed diets, and monitoring adherence and response to diets. It was pointed out that the qualification requirements in the proposed regulations would allow persons majoring in food management to qualify although such persons do not have educational preparation for clinical nutrition activities. The comments further suggested that the masters degree should be the minimum educational requirement. The proposed regulation would not permit a person to qualify who had a baccalaureate degree in a field other than in food and nutrition but did have a masters degree in the area. The regulations have been changed to require a baccalaureate or advanced degree with major studies in food and nutrition or dietetics.

Dietician education (Qualification)

The largest number of comments were on the qualifications of the social worker. Many commenters expressed the opinion that the need of the ESRD patient is for psychosocial evaluations and for recommending changes in treatment based on the patient's current psychosocial needs and for direct social work interventions. This activity is considered to require the background for a masters degree with specialization in clinical practice; the usual baccalaureate programs in social work were not felt to provide the requisite background in counseling of ESRD patients. The definition of social worker in section 405.2102(r)(6)(i) and minimal

Social (worker)

service requirements for ESRD facilities (sections 405.2163(b) and 405.2171(b)) were rewritten to reflect this major consideration.

A lesser number of comments related to the person who has been functioning as a social worker presently involved in ESRD care, but who does not have the masters degree and specialization in clinical practice. The definition (section 405.2102(r)(6)(ii)) now accommodates this person, provided the individual has served for at least two years as a social worker, one year of which was in a dialysis unit or transplantation program prior to the effective date of these regulations, and provided this person has established a consultative relationship with a social worker who is qualified by the masters degree and specialization in clinical practice.

The qualifications for a registered nurse responsible for the nursing service have been changed to permit the nurse to qualify whose entire work experience has been in ESRD patient care. The requirement has been changed to permit an alternative means for the nurse to qualify—if he or she has 18 months of experience in nursing care of patients on maintenance dialysis, or in nursing care of patients with a kidney transplant, including training and experience in the dialysis process. The provision in the proposed regulations for an exception in situations where the nurse with required experience was not available has now been removed. It is believed that, by lowering the amount of experience required from 24 months under interim regulations to 18 months, as well as retaining the minimal requirement for only one such qualified nurse per facility at a given time, there should be no need for the exception provision. It is also believed that 18 months of training and experience should be the minimum for assuming responsibility for the nursing service. A slight change has been made in the requirement for the registered nurse in charge of self-care dialysis training—the 3 months of experience in a Renal Dialysis Center or Renal Dialysis Facility which offers self-care dialysis training has been changed to 3 months of experience in training patients in self-care dialysis.

The requirement for Medical Record Practitioner (Qualified) has been changed to provide for qualifications at any level of approved training. One commenter has suggested that the proposed regulations as written could exclude otherwise qualified Directors of Medical Record Libraries. The changes made were developed in consultation with the American Medical Record Association.

A minor change has been made in the definition of Physician-Director (Qualified) to allow the person to qualify with 12 months experience as director of a dialysis facility or a transplantation facility. The change has simply removed the designation of ESRD facility and was necessitated by the redefinition of an ESRD facility as an approved facility; such approval was not available during the prior five year period.

Many comments were received suggesting definitions for various other personnel which are needed in the treatment of ESRD patients. The types of personnel suggested were (1) occupational therapists, (2) psychologists, (3) vocational rehabilitation counselors, (4) dialysis technicians, and (5) nephrologists. It is believed that for the purpose of these regulations the terms nephrologist, psychologists, and vocational rehabilitation counselors do not need to be defined.

The comments pointed out that occupational therapists, for example, perform an important role in ESRD patient care and that psychologists are often needed in psychological evaluations of ESRD patients. The importance of occupational therapists was considered in the drafting of the final regulations but this discipline was not included as required staff of an ESRD facility. The requirement for staffing and services has been written as a minimum; this is not to prevent attending physicians and ESRD facilities from making use of whatever expertise is needed for each patient. At this time, it is believed that Federal regulations should not require this desirable expertise for all patients. Therefore, the regulations do not require use of the services of occupational therapists. Similarly, there is no requirement for the use of the services of psychologists, and vocational rehabilitation counselors. As to the definition of nephrologist, we believe that term is sufficiently well understood in the medical community as to obviate a specific definition here.

Although we agreed with the commenters who indicated a need for the definition of the dialysis technician, we believe that the newness of this discipline preclude clear definition at this point in time. Additional time will permit observation of this emerging health occupation in facilities heretofore unsurveyed and will enable us to review studies which have been conducted as well as the work of interested individuals and organizations who are currently grappling with the definition and entry level knowledge and skills requirements for this paraprofession.

Several commenters suggested that a definition of a Chief Executive Officer (Qualified) be added in the definitions of qualified personnel and suggested that the minimum qualifications should include a masters degree in hospital administration. Such a definition had not been included in the proposed regulations; however, the responsibilities of the Chief Executive Officer were listed (see Section 405.2136(c)(3)). The proposed regulations reflect the belief that the scope of the facility's operations and administrative needs varies considerably according to the size of the facility. In a hospital-based ESRD facility, it was felt that these responsibilities might well be assumed by the hospital administrative staff whereas in a small dialysis facility, the Physician-Director would often be able to assume the responsibilities. The regulations have been rewritten to include minimum qualifications for the Chief Executive Officer, taking into consideration the range of background and experience which would qualify an individual to assume the responsibilities of Chief Executive Officer.

Several other definitions have been altered or added. Because of comments indicating patient concern about treatment in an ESRD facility in a network area other than where the patient resides, the definition of ESRD Network has been altered to eliminate the statement that the ESRD facilities in a network area furnish the necessary care for ESRD patients in the designated area. In addition, to more clearly indicate the types of reviews to be undertaken by the Medical Review Board, the term Medical Care Evaluation Study (MCE) has been used and is, therefore, defined in this Section 405.2102.

There were several suggestions that "Informed Consumer" (as required representatives on the Network Coordinating Council) be defined in regulations. These suggestions, however, varied considerably in their recommended definitions for such persons. Some suggested a patient who had undergone transplantation, others suggested manufacturers of ESRD equipment, and still others suggested that "informed consumers" should be representatives of consumer groups. It was decided at this time not to define in regulations which "consumers" should be included in NCC. It was also decided not to include a definition for a qualified pharmacist at this time or to establish by regulation the duties of a qualified pharmacist in an ESRD facility.

Comments on network area designations. (Section 405.2110). A large number of comments were received requesting changes in the area designations of several networks. Many of the comments contained detailed information on ESRD referral patterns. In addition, subsequent to publication of the proposed regulations on July 1, 1975, the final designations were made for the Health Service Areas (HSA's), required pursuant to the Public Health Service Act, as amended by P.L. 93-641. For these reasons, the Department has made changes in some of the ESRD network area designations.

The previously proposed regulations designated 29 network areas. As a result of modifications based on comments and on designated Health Service Areas, these final regulations now designate 32 network areas.

The largest single change with respect to the number of networks was in the division of previously designated network area #23 which encompassed the District of Columbia, the States of Maryland and West Virginia, and the State of Virginia excluding the counties of Scott and Washington into smaller network areas. Information received subsequent to the publication of the proposed regulations indicate that it would be undesirable to include in one network the large geographic area originally proposed. Comments received unanimously support the redesignation of this network area into three smaller network areas.

A large number of comments on network area designations requested that New Jersey be designated as a separate, single Network. Data and information

received subsequent to the publication of proposed regulations indicate a substantial reduction in the percentage of New Jersey patients being referred for treatment in out-of-state ESRD facilities. Therefore, the proposed network area #24 has been changed and New Jersey has been designated as Network #25.

The comments on proposed Network #9 were overwhelmingly in opposition to he "division of Illinois." Network #15 has been realigned to include the State f Illinois except for three counties in Network #8 and four counties which remain in Network #9. Exclusion of these ounties from the Illinois Network #15 s based on facility affiliation arrangements and is congruent with the designated Health Service Areas surrounding he St. Louis and Davenport SMSA.

A number of comments suggested that labama could function as an ESRD etwork and should be designated as uch. Data presently available, however, how that Alabama has only one Medicare approved transplant hospital. One f the major criteria used in designating network areas was the requirement hat there be two transplantation centers for each network area. This requirement was made to help assure that the eview of the quality of transplantation ervices could be conducted by peer professionals not directly involved in the are which is being reviewed. Exceptions this criterion have been granted only n Puerto Rico and Hawaii, where compliance with this requirement is impractical. Since Alabama has only one transplantation hospital it was decided that t this time the network area should remain unchanged. Therefore, the States Alabama, Mississippi, and Tennessee main as a single network area.

Several other changes have also been ade in the network areas. The portion the Navajo Territory of San Juan ounty, Utah has been added to Network 6 with the States of Arizona and New exico. There has been a realignment of veral counties in the Upper Peninsula Michigan and in Wisconsin which affects Networks #7, #13 and #14. Network #16 now consists of the State of diana; Dearborn County, Indiana had een proposed as part of Network #17. here has been a realignment of several unties in Network #22. Several countes in the States of Arkansas and Missouri are now included in Network #18. even western counties of Nebraska ave been included in Network #5.

Area designations which have not een changed are Networks #1, #3, #4, 11, #12, #19, #20, #21, #26, #27, 28, and #29.

Comments on ESRD networks (section 5.2112) and Network Coordinating uncils (section 405.2111). There were any comments which noted that while e proposed regulations established the ructure and functions of network ganizations, i.e., Network Coordinating uncil and Medical Review Board, no atement was included about how or e extent to which the organizations ere to be funded. The Secretary will pport the reasonable operating costs of designated Network Coordinating Councils and Medical Review Boards. It is felt that no specific statement in this regard is needed in these regulations. Included with some of the comments on funding of network activities were wide ranging estimates of the costs of these activities. Other comments reflected divergence of interpretation of the functions of network organizations. As a result, although the provisions of proposed regulations have not undergone major changes, the sections dealing with networks and network organizations have been rewritten in an effort to make them more clear. Interpretative guidelines and other materials and means of technical assistance will be provided to assist in carrying out the meaning and intent of the regulations.

Comments on the size of networks included several to the effect that the networks were too small; however, most comments indicated that networks were too large and would result in the Network Coordinating Council being too costly and cumbersome. The regulations have been changed to require that Network Coordinating Councils composed of more than twenty persons appoint an executive committee of twenty or less to assume the responsibilities of the Council. Several comments had indicated that large Councils need such an executive committee. Despite this change, the membership of the Network Coordinating Council is still representative of the ESRD facilities in the network area.

A number of commenters suggested changes in the composition of the Network Coordinating Council. Some would increase the number of consumers on the Council (up to 40 percent of the membership) and suggest that representatives of consumer groups be members of the Council. Other suggestions were that the various disciplines required on the Council have representatives selected by professional organizations in the network area. Many other disciplines were suggested for membership on the Council. It was also suggested that the public sector be represented and that State and local health planners be represented on the Network Coordinating Council. There were merits to all the suggestions but, in the interest of keeping the Council to workable size, the decision was made to limit its composition. These final regulations now require the following additional members if not included among the facility representatives: Transplant surgeon, Internist-nephrologist, Pediatrician, Chief executive officer, Qualified dietitian, Qualified nurse responsible for nursing services, Qualified social-worker, Dialysis technician. Three informed consumers, Director of a histocompatibility testing laboratory, and Representative of an organ procurement agency.

A major area of comment was with respect to the functions of the network organizations: some comments suggested that the functions be stated in more detail and other comments suggested that the network organizations be given more authority to carry out functions such as determinations of personnel qualifications. The preamble in the notice of proposed rulemaking had outlined the role of the Network Coordinating Council as a liaison between the Federal government and available community resources. These final regulations provide the flexibility for member facilities of a network to work together as a Council to set objectives which it perceives will meet the needs of ESRD patients in the network area and for the member facilities to work together to achieve those objectives. The Council would provide information to the Secretary and would make recommendations to member facilities. The Federal government will furnish technical assistance to Network Coordinating Councils in identifying the needs of the area and in achieving network objectives.

Comments on Medical Review Boards (section 405.2113). As with the Network Coordinating Council, there were comments that additional disciplines be included as members of the Medical Review Board. One area of concern about the proposed regulations was the possibility that the board might not have a majority of physicians; it was suggested that a change be made to require a majority of physicians on the Board. The opinion was also expressed that the Medical Review Board should be composed entirely of physicians. Other comments suggested that members of the Board be selected by peer organizations (e.g., the registered nurse to be selected by a professional nurse association) rather than by the Network Coordinating Council. It was also suggested that reviewers from outside the network be requested to review questionable facilities.

These final regulations have been rewritten to better delineate the functions of the Medical Review Board, to clarify the relationship between the Network Coordinating Council and the Board, and to provide a majority of physicians on the Board. The functions of the Board are specified as: (1) evaluation of the comparative performance of facilities based on aggregate data from the Medical Information System, (2) coordination of the performance of Medical Care Evaluation Studies in which each ESRD facility will participate, and (3) as necessary, performance of in-depth studies based on information from (1) and (2) above. Thus the functions have been restated to emphasize the review of overall quality of care. The regulations now provide for the Network Coordinating Council, not only to establish the Medical Review Board, but also to monitor the functions of the Board as well. In addition, there is provision for the Board to be composed of a maximum of seven members rather than the five members originally proposed. This latter change will provide a majority of physicians, a lesser burden for each member, and for specialists as needed for review.

Comments on relationships of Network Organizations to Health Care Review and Planning Organizations. (Section 405.2114). Many commenters outlined strong opposition to the relationships between the Network Coordinating Council and Health Systems Agencies

(HSA's) and between the Medical Review Board and the Professional Standards Review Organizations (PSRO's) as written in the proposed regulations. The commenters generally expressed the opinion that ESRD patient care is too complex to be reviewed by other than experts in ESRD; that the functions of the Council and of the Board would become too fragmented in trying to relate to the HSA's and PSRO's since ESRD network areas in some instances would overlap as many as 12 HSA's and as many as eight PSRO's.

The Public Health Service Act, as amended by the National Health Planning and Resources Development Act of 1974, P.L. 93–641 provides for the establishment of Health Systems Agencies and State Health Coordinating Councils (SHCC's) and details their functions. Similarly, Part B of Title XI of the Social Security Act provides for PSRO's to have review responsibility for the health care services provided under Titles XVIII, XIX and V of the Social Security Act. Section 226(g) of the Act (42 U.S.C. 426(g)) mandates a Medical Review Board to screen the appropriateness of patients for the proposed treatment procedures. It is implicit that recognition must be made of relationships between these various organizations (as stated in these regulations) to avoid duplication of activities and to make available to PSRO's, HSA's, and SHCC's the ESRD expertise in the network area. To establish these relationships, these regulations provide for the Network Coordinating Council to develop written arrangements with PSRO's established established under Public Law 93–641 which will describe the procedures by which the Network Coordinating Council will integrate its planning responsibility with the planning responsibilities of HSA's and SHCC's. Similarly, the Medical Review Board will develop written arrangements with PSRO's established under Part B of Title XI of the Social Security Act which will describe the procedures by which the Board will integrate its medical review responsibility with the review responsibilities of PSRO's.

On a continuing basis, these regulations require that the Network Coordinating Council accept planning responsibility as requested by the HSA's and SHCC's and for the Medical Review Board to accept review responsibility as requested by the PSRO's. It is expected that, because of the complex nature of ESRD patient care and ESRD patient referral patterns, HSA's and PSRO's will recognize and make use of the expert assistance which the ESRD network organizations will be capable of providing.

Comments on minimal utilization rates. (Sections 405.2120–405.2130). The Secretary is directed by Section 226(g) of the Act (42 U.S.C. 426(g)) to limit Medicare reimbursement for kidney transplant and dialysis services to facilities meeting such requirements as he may by regulation prescribe provided that such requirements include at least requirements for minimal utilization rate for covered procedures. Many comments were directed to the minimal utilization rate portions of the proposed regulations. A major comment was that there should be no minimal utilization rates because evidence is lacking that the number of procedures performed correlate either with quality improvement or cost efficiency. Although it is true that there is a lack of conclusive evidence which establishes with certainty a relationship between utilization rates and the efficiency and effectiveness of care, it can be rationally assumed that such a relationship does exist and thus requirements for meeting minimum rates. As required by law, minimum utilization rates have been retained.

Among the comments were several expressing the opinion that the minimal utilization rates proposed were too high and others suggested that they were too low. In analyzing the impact of the transplantation center minimum utilization rates contained in the July 1, 1975, Notice of Proposed Rule Making, it is clear that the rates were so high as to preclude a substantial number of facilities currently participating in the ESRD program under the interim regulations from further participation in the program. This adverse effect on access to care has been addressed by a reduction in the minimal utilization rates for transplantation centers from 25 to 15 transplants annually for unconditional status and from 14 to 7 transplants annually for conditional status. Because of the new lower rates, it was considered unnecessary to have an exception category for transplantation centers. Since renal transplantation is a one time or discrete procedure, exception status for the purpose of access is not a consideration. The rates have been lowered to the point where most primary research or pediatric referral centers should meet this condition in order to qualify for conditional status under the long term program. At such time as continuing ESRD program experience and data developed from the ESRD medical information system demonstrate the degree of correlation between utilization rates and quality improvements and cost efficiency, consideration will be given to amending the regulations on minimal utilization rates for transplantation.

The minimal utilization rates for ESRD dialysis facilities have not been changed; the concerns expressed in comments have been taken into consideration through other changes. For example, it was suggested that facilities which furnish essential "back-up" service for ESRD patients during inpatient stays and yet provide only a small amount of dialysis to outpatients should be permitted a separate minimal utilization rate classification or should be exempt from the requirement. Following these suggestions, minimal utilization rates for dialysis facilities which perform greater than 20 percent of their dialyses on outpatients are unchanged. For those dialysis facilities performing 20 percent or less of their dialyses on outpatients, however, the minimal utilization rates have been changed to be the same as those for a facility located outside a Standard Metropolitan Statistical Area, (see Section 405.2130); the computation of the facility rate includes both inpatient and outpatient dialyses. The exception status for those dialysis facilities located in areas where there are too few patients to allow the facility to meet the required rates but where the facility is needed to overcome what would otherwise be inadequate patient access to dialysis, has been retained in the regulations.

Provision is made for new transplantation and dialysis facilities to come into the ESRD program under conditional status on the basis of a written plan for achieving unconditional status.

In response to comments, the basis for computing utilization rates for dialysis facilities has been changed to take into consideration fluctuations in rates of dialysis.

Several comments suggested that rates for dialysis facilities should consist only of the number of dialyses performed and not include the number of stations in the facility. The minimal utilization rates for dialysis facilities remains the same and includes both dialyses and stations to assure efficient utilization of stations. However, a change has been made to exclude from the computation of rates any station at which at least six ESRD patients have been trained in self-dialysis in the last year. The purpose of this change is to encourage, where medically appropriate, the utilization of this less expensive treatment modality.

Comments on compliance with the requirements of Federal, State and local laws. (Section 405.2135). One commenter recommended total deletion of this condition on the apparent assumption that network organizations will be charged with enforcement of State and local laws. It was recommended that such enforcement continue to remain in the hands of appropriate government agencies. For purposes of clarification, it is stated here that no network organization will be charged with enforcement of any Federal, State, or local law and that such enforcement will not be affected by the establishment of ESRD networks. Appropriate government agencies will continue to be charged with enforcement of laws. The purpose of this part of the regulations is to make compliance with such laws a condition for granting approval to ESRD facilities under the Medicare program; a similar requirement is imposed on all facilities under Medicare. No change was made in this requirement.

Comments on governing body and management. (Section 405.2136). One comment was made that this requirement is so vague and broad in scope as to hinder adequate documentation of compliance. Although it is felt that the requirement is sufficiently explicit, interpretive guidelines will be forthcoming to assist facilities in providing the necessary documentation.

Several commenters suggested that the provision for disclosure of ownership is unjustified and possibly illegal.

As previously discussed, Section 226(g) of the Social Security Act (42 U.S.C. 426) authorizes the Secretary to limit reimbursement for kidney transplant and dialysis services to facilities meeting such requirements as he may by regulation prescribe. The requirement for disclosure of ownership is believed to be justified on the basis that there is a rational and pervasive need for this provision. The ESRD program is new and the total annual patient care benefit cost is estimated to reach at least one billion dollars within several years. Because of the newness of the program and its estimated costs, it is necessary to gather data and to refine the system as quickly as possible. There is a need for monitoring the costs of the program; as such, there is a need to have knowledge of ownership and of relationship of the ownership of a facility to other facilities furnishing similar services. The disclosure of ownership provision is consistent with Section 405.2113(c) which does not permit a person serving on the Medical Review Board to review the ESRD services of a facility in which that person has a financial interest. Because of these reasons, it is believed that the disclosure of ownership provision is not illegal, it is justified for program purposes, and is unchanged.

The comments on operational objectives indicated confusion over the requirement that "criteria defining patient eligibility for services are developed * * *". As a result, a slight editorial change has been made in this part (Section 405.2136(b)(3)) which now reads that "admission criteria are adopted by the facility and are readily available to ensure equitable access to such service."

A slight change in the responsibilities of the chief executive officer has been made by deleting the word "medical" in Section 405.2136(c) from the expression "* * * and act upon medical recommendations made by * * *".

The comments on the institutional planning requirement consisted of questions on how this provision related to planning agencies and how the provisions were to be interpreted. However, as previously discussed, several comments also suggested that some requirements could be duplicative. This requirement for institutional planning is duplicative since it is presently a requirement for Medicare-approved hospitals; this requirement, therefore, has been deleted. Although the deletion leaves the non-hospital operated ESRD facilities with no specific requirement for institutional planning, it is believed that there are requirements in other sections of the regulations which sufficiently mandate an ESRD facility to plan for future furnishing of ESRD services.

Several editorial changes have been made as a result of comments on personnel policies and procedures which indicated some confusion with patient care policies (Section 405.2136(f)). In addition, several comments suggested additional requirements with respect to infection control, particularly control of hepatitis. A suggestion that the facility provide for professional development was considered to be sufficiently covered under the responsibilities of the Chief Executive Officer.

A number of comments were made with respect to patient care policies; most were concerned with scheduling of hours for dialysis at the convenience of patients. The regulation now reads that whenever feasible, hours for dialysis are scheduled for patient convenience. The requirement for periodic review of patient care policies has been amended to indicate that the review activity need not be conducted solely by physicians and nurses. The suggestion to eliminate the word "regularly" from scheduled conferences to evaluate patient progress has been rejected. It was believed that such evaluation must be made regularly (see Section 405.2137 (a) and (b)).

To avoid the implication that a facility must remain open at all times, Section 405.2136(g)(2) has been changed to read that the governing body ensures that medical care is available for emergencies, 24 hours a day, 7 days a week.

It was suggested that there be a requirement that all ESRD facilities maintain an open staff for all nephrologists. It was believed that an open staff requirement might at this time be seen as interfering with a facility's prerogative to pass on medical staff qualifications. Further it was recognized that ESRD networks and facilities should concern themselves with the utilization of qualified physicians. It is assumed, therefore, that decisions concerning the granting of privileges in a facility will be based upon the physician's professional qualifications and the facility's capacity to accommodate the physician's patients.

Comments on patient care plans. (Section 405.2137). This condition has been rewritten in greater detail to insure that each patient receives a periodic evaluation with respect to the appropriate modality of care. In revising the condition to provide for evaluation of the long-term program as well as a patient care plan, several of the comments were incorporated. The requirement now is more specific in stating who is involved in making evaluations in the long-term program and in the patient care plan. In addition, it is stated that each patient must be evaluated in the long-term program not less frequently than every 12 months. The review of the patient's progress in the patient care plan must not be less frequent than monthly; a comment that this evaluation be made not less than twice monthly was believed to be more frequent than necessary for most patients.

Comments on patient's rights. (Section 405.2138). The condition on patient's rights has been reorganized to required standards covering: (1) informed patients, (2) participation in planning, (3) respect and dignity, (4) confidentiality, and (5) a grievance mechanism. There were a number of comments suggesting changes which have not been made, not because the comments were unacceptable, but because the suggestions were considered inappropriate for regulations. For example, it was suggested that there be provisions for a translator for any patient with a language barrier rather than when a significant number of patients exhibit a language barrier; it was believed administratively more feasible to retain the present requirement. A comment suggested the addition of the right to refuse treatment but it was believed that this need not be in regulations; however, the right to refuse to participate in experimental research was retained.

Comments on medical records. (Section 405.2139). This section remains essentially unchanged; the changes in other parts of the regulations include suggestions made in the comments on medical records.

Comments on physical environment. (Section 405.2140). This section has been enlarged slightly to provide more detail with respect to hepatitis control which was the concern of several commenters. The regulations take note of the importance of infections control and specifically hepatitis, but refrain from requiring a separate isolation treatment area with separate staff at this time. The area of hepatitis control will be kept under review for possible future changes in regulations and interpretive guidelines.

Concern was expressed that testing of emergency procedures while patients are being dialized might present a hazard to the patients. The requirement that there be emergency procedures with which the facility personnel are familiar is designed to enhance the safety of the environment. Interpretive guidelines will provide assistance on how the testing of emergency procedures can be carried out. The regulations have not incorporated references to publications describing minimum requirements for construction and equipment; the development of interpretive guidelines will take into consideration such publications. However, certain requirements have been added to these regulations to increase the safety of the environment through the provision of ground-fault interrupters in electrical circuits to equipment and the provision of an alternate electrical power source from an emergency generator.

Comments on affiliation agreement or arrangement. (Section 405.2160). The comments on this section indicated that the proposed regulation was unclear, particularly with respect to emergency and non-emergency admissions to the affiliated facility. The portion of the requirement pertaining to provision of care in emergencies has been deleted to simplify the requirement. It is believed that this change, together with the changes in definition of ESRD facilities (see Section 405.2102(e)) has clarified the requirement.

Comments on director of a renal dialysis facility or renal dialysis center. (Section 405.2161). One commenter raised the question whether the proposed regulation was in conflict with Section 1801

of the Social Security Act in that the regulation sets up requirements as to which physicians may treat which patients. This regulation is intended only to assure that the ESRD services furnished by the facility are under qualified direction. The patient is under the care of his or her own physician, who may also be the Physician-Director. As Director, this physician is responsible for planning, organizing, and supervising the professional ESRD services of the facility.

Another comment contained the recommendation that the regulations specify the Director be responsible for a Staff Development Plan for all personnel. The regulations require a facility to assure that all personnel of the facility participate in educational programs on a regular basis (Section 405.2136(d)(6)) and further prescribe that the Chief Executive Officer has the responsibility for assuring that all employees have an opportunity for continuing education and related development activities (Section 405.2136(c)(3)(viii)). These parts of the regulations were considered to provide adequate assurance for a staff development program for all employees. The additional responsibility for the physician-director in assuring adequate training of the nurses and technicians in dialysis techniques was designed to provide for safe procedures and techniques and to assure that the dialysis staff are well versed in current practice.

Several commenters suggested that Section 405.2161 be changed slightly so that the physician-director is not responsible for "training" but is responsible for "assuring adequate training". This change was made as it provides more flexibility in the actual training but still retains the requirement that the physician-director assures that there is training.

Comments on staff of a renal dialysis facility or renal dialysis center. (Section 405.2162). This section has been edited to: (1 substitute the word "physician" in place of M.D., (as defined in Section 1861(r)(1) of the Social Security Act, (2) indicate that one currently licensed health professional is on duty to oversee ESRD patient care, and (3) add that on adequate number of personnel are present to meet the needs of patients.

One commenter suggests that an L.P.N. is not sufficiently qualified to be left in charge of ESRD patients; conversely, one hospital commented that its nursing service was composed entirely of L.V.N.'s (Licensed Vocational Nurses) and suggested that the nurse responsible for the nursing should be an L.V.N. Until such time as there is a better consensus on qualifications of staff as well as training of nephrology personnel, it is believed that the regulations should require the qualified registered nurse to be in charge of the nursing service and to allow the L.P.N. to oversee ESRD patient care. For purposes of this discussion, the licensed practical nurse and the licensed vocational nurse are considered equivalent in qualification. It is recognized that this regulation is a minimum requirement; larger facilities should staff according to their needs with the adequacy of staff being determined by the adequacy of the process and outcomes of patient care. Ratios of staff to patients have not been used in these regulations because at the present time, ratios in themselves cannot be used as sole determinants of good patient care.

Comments on minimal service requirements for a renal dialysis facility or a renal dialysis center. (Section 405.2163). A large number of commenters suggested changes in this section, particularly as related to the social and dietetic services. Revision has been made in response to these comments. The proposed regulations were intended to provide a minimal base for social and dietetic services upon which each facility would add such responsibilities and qualified personnel sufficient to meet the needs of the ESRD patients being treated. However, the consensus of comments from nephrology social worker and dietitian groups pointed out that the responsibilities listed in the proposed regulations were unrealistically limited and did not reflect the extent of involvement of these disciplines in ESRD therapy in current practice. The social workers pointed out that the real need is for psychosocial evaluations and counseling rather just social evaluations. There is a similar need for dietetic evaluation and counseling. The minimum education and experience of personnel qualified to carry out such added responsibilities is reflected in the changes in definitions of qualified ESRD personnel (Section 405.2102(r)(2) and (6)).

While the proposed regulations stated that laboratory services were to be performed by a Medicare-approved laboratory, it was recognized that the dialysis process requires certain monitoring procedures. Exceptions have been granted which permit hematocrit and clotting time determinations to be made on the premises of an approved ESRD facility under the direction of a physician.

Commenters pointed out that an ESRD facility should not be required to be responsible for installation and maintenance of equipment and for the ordering of supplies for the self-care dialysis patient. In response to this, the section on self-care dialysis support services has been rearranged to indicate that an ESRD facility is required to assist the ESRD patient, as needed, in making arrangements for such services.

Comments on director of a renal transplantation center. (Section 405.2170). The same change which was made for the renal dialysis facility and renal dialysis center has been made in this section; the requirement that the director be responsible for training of staff has been modified to responsibility for assuring training of staff.

Comments on minimal services requirements for a renal transplantation center. (Section 405.2171). The changes which were made for the renal dialysis facility and renal dialysis center have similarly been made in the requirements for social services and dietetic services (see discussion of comments on Section 405.2163). In addition, changes have been made in laboratory services (see discussion of comments on histocompatibility testing).

A section has been added that requires that if a renal transplantation center utilizes the services of an organ procurement agency to obtain donor organs, the organ procurement agency must furnish these services under an arrangement (Section 405.2171(e)).

A number of comments were made that there were few requirements for renal transplanation centers in contrast to many requirements for ESRD dialysis facilities. As discussed earlier in this preamble, a renal transplantation center must meet all Medicare requirements in this subpart except those parts specifically for renal dialysis facility or renal dialysis centers. These, too, must be met if the renal transplantation center also furnishes dialysis services.

(Secs. 226(g), 1102, 1861, 1862(a), 1871, 1874, Social Security Act; 86 Stat. 1464, 49 Stat. 647, as amended, 79 Stat. 325, 331, 332, and 340; 42 U.S.C. 625(g), 1302, 1395x, 1395y (a), 1395hh, 1395kk.)

Effective Date: The amendments shall be effective September 1, 1976.

(Catalog of Federal Domestic Assistance Programs No. 13.800, Health Insurance for the Aged—Hospital Insurance.)

Dated: March 25, 1976.

J. B. CARDWELL,
Commissioner of Social Security.

Approved: May 24, 1976.

MARJORIE LYNCH,
Acting Secretary of Health, Education, and Welfare.

Part 405 of Chapter III of title 20 of the Code of Federal Regulations is amended as set forth below:

1. Section 405.1031 is amended by revising the introductory paragraph to read as follows:

§ 405.1031 Condition of participation—complementary departments.

Participation is not limited to hospitals which have surgery, anesthesiology, dental, or rehabilitation departments or services, but if these departments or services are present, there are effective policies and procedures, relating to the staff and the functions of the service(s) in order to assure the health and safety of the patients. If the hospital provides end-stage renal disease services, reimbursement for such services will not be made unless the hospital also meets the Conditions for Coverage of Suppliers of End-State Renal Disease Services, Subpart U of this Part. If a hospital laboratory department wishes to provide histocompatibility testing, reimbursement for such services will not be made unless the laboratory department also meets the appropriate requirements in Subpart M of this Part (§ 405.1901(c)).

2. In § 405.1310 a new paragraph (m) is added to read as follows:

§ 405.1310 Definitions.

* * * * *

(m) *Histocompatibility testing.* Laboratory test procedures which determine compatibility between a potential donor organ and a potential organ transplant recipient.

3. In § 405.1314 a new paragraph (b) (13) is added to read as follows:

§ 405.1314 Condition—clinical laboratory; tests performed.

* * * * *

(b) *Standard: Procedures and tests—competency.*

* * * * *

(13) Notwithstanding paragraph (b) (1) of this section, if the laboratory performs tests in the specialty of histocompatibility testing, the director or supervisor:

(i) Holds an earned doctoral degree in a biological science or is a physician and

(ii) Subsequent to graduation has had 4 years of experience in immunology, 2 of which have been in histocompatibility testing.

4. In § 405.1317, a new paragraph (b) (8) is added to read as follows:

§ 405.1317 Condition—quality control.

* * * * *

(b) *Standard: Quality Control System—Methodologies.*

* * * * *

(8) *Histocompatibility testing.* In ad-iition to the standards for quality con-rol in immunohematology, paragraph b)(4) of this section, and serology, aragraphs (b)(2)(i) and (b)(2)(ii) of his section, which are applicable to the istocompatibility testing laboratory, the istocompatibility testing laboratory tilizes the following control systems and alidation methods for the performance f tests in the following:

(i) for renal allotransplantation: (A) rossmatching of potential recipients nd donors before transplantation is per-ormed with one or more techniques sing the most reactive and most recent era;

(B) HL-A serologic typing of both onor and recipient which include at ast those antigens detectable with rum capable of defining the same ntigens as those definable by the Na-onal Institutes of Health serum ay(s); and,

(C) Characterization for antibody gainst histocompatibility antigens in rum from potential recipients of organ tissue grafts.

(ii) For transfusions and bone mar-w transplants the tests in paragraphs)(i)(A) and (8)(i)(B) of this section e required.

(iii) For disease association studies, aragraph (8)(i)(B) of this section pplies.

(iv) Mixed lymphocyte cultures or her recognized methods to detect cellu-r—defined antigens are performed in cordance with prescribed methods.

(v) Procedures are established regarding freezing of lymphocytes and to provide for a comprehensive panel of fresh and/or frozen lymphocytes.

(vi) The reactivity of cell panels used for antibody detection is tested at least twice a month with appropriate known antisera.

(vii) The laboratory must also: (A) At least once each month have each individual performing tests be given a previously tested specimen as an unknown to verify their ability to reproduce test results and the results of such testing shall be recorded and,

(B) Participate in at least one national or regional cell exchange program, if available, or develop an exchange system with another laboratory in order to validate interlaboratory reproducibility.

5. Section 405.1901 is amended by redesignating paragraph (c) as paragraph (d), redesignating paragraph (d) as paragraph (e), and adding a new paragraph (c) to read as follows:

§ 405.1901 The certification process.

* * * * *

(c) A hospital which is a participating provider of services, for a nonhospital-operated renal dialysis facility as defined in § 405.2102(e)(3), or a laboratory facility that is approved to participate in the Medicare program which, notwithstanding approval pursuant to Subpart J or Subpart M, also meets the requirements in §§ 405.1314(b)(13) and 405.1317 (a), (b)(2) (i) and (ii), (b)(4), and (b)(8) and, when services are furnished in the specialty of tissue pathology, also meets the requirements in §§ 405.1314(b)(8)(i) and 405.1317 (a) and (b)(6)(ii), and which is found to be in compliance with each of the applicable Conditions for Coverage of Suppliers of End-Stage Renal Disease Services prescribed by the Secretary (see Subpart U), may become a supplier of End-Stage Renal Disease services pursuant to section 226(g) of the Social Security Act upon being approved therefor by the Secretary.

* * * * *

6. A new § 405.1912 is added to read as follows:

§ 405.1912 Special procedures for approving end-stage renal disease facilities and the expansion of services in approved facilities.

(a) *Considerations for approval.* An ESRD facility which wishes to be approved for coverage, or which wishes any expansion of dialysis services to be approved for coverage in accordance with Subpart U of this Part, must secure the Secretary's determination thereunder. In addition to the certification by the State agency referred to in § 405.1902, data furnished by network organizations and recommendations of the Public Health Service, concerning the contribution of a facility to the furnishing of end-stage renal disease services in its network and concerning the facility's compliance with professional norms and standards (see Subpart U of this Part), shall be considered by the Secretary in determining whether to approve a facility for coverage or for any expansion of services under the End-Stage Renal Disease Program. The facility will also be required to submit data pertaining to its qualifications for approval or for any expansion of services, for consideration in the Secretary's determination.

(b) *Determining compliance with minimal utilization rates: time limitations.* (1) *Unconditional status.* A facility which meets minimal utilization requirements will be assigned this status as long as it continues to meet these requirements.

(2) *Conditional status.* A conditional status may be granted to a facility for not more than 2 consecutive calendar years and will not be renewable (see § 405.2122(b)). Its status may be examined each calendar year to ascertain its compliance with Subpart U.

(3) *Exception status.* Under unusual circumstances (see § 405.2122(c)) the Secretary may grant a time-limited exception to a facility which is not in compliance with the minimal utilization rate(s) for either unconditional status or conditional status. This exception status may be granted, and may be renewed on an annual basis, under circumstances where rigid application of minimal utilization rate requirements would adversely affect the achievement of ESRD program objectives.

(c) *New applicant.* A facility which has not previously participated in the ESRD program must submit a plan detailing how it expects to meet the conditional minimal utilization rate status by the conclusion of 1 calendar year of its operation under the program and meet the unconditional minimal utilization rate status during the third calendar year of its operation under the program.

(d) *Notification.* The Secretary will notify each facility and its network coordinating council of its initial and its subsequent minimal utilizaton rate classification.

(e) *Failure to meet minimal utilization rate.* A facility failing to meet standards for unconditional status or conditional status, or if applicable, for exception status, will be so notified at the time of such classification.

(f) *Interim regulations participant.* A facility previously participating under the interim regulations will not be approved under the program established by Subpart U until it has demonstrated that it meets all the applicable requirements of this Subpart, including the appropriate minimal utilization rate. It may continue under the interim program only for a period not to exceed 1 year from the effective date of these amendments (see § 405.2100(c) of this part). During this period it may demonstrate its ability to meet the appropriate minimal utilization rate. Failure to qualify under this Subpart will automatically terminate coverage of such facility's services under the ESRD program at the end of such year.

7. Part 405 of Title 20, Code of Federal Regulations, is amended by adding a new Subpart U, and an Appendix, reading as follows:

Subpart U—Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services

Sec.
405.2100 Scope of subpart.
405.2101 Objectives of end-stage renal disease (ESRD) program.
405.2102 Definitions.
405.2110 Designation of ESRD network areas.
405.2111 Designation of network coordinating councils.
405.2112 Designation of ESRD networks.
405.2113 Medical review board.
405.2114 Relationship of ESRD networks to health care review organizations and to health service planning organizations.
405.2120 Minimal utilization rates: general.
405.2121 Basis for determining minimal utilization rates.
405.2122 Types and duration of classification according to utilization rates.
405.2123 Reporting of utilization rates for initial classification.
405.2124 Calculation of utilization rates for comparison with minimal utilization rates(s) and notification of status.
405.2130 Condition: minimal utilization rates.
405.2131 Condition: Provider status: renal transplantation center or renal dialysis center.
405.2132 Condition: fulfillment of service needs in network.
405.2133 Condition: furnishing data and information for ESRD program administration.
405.2134 Condition: membership in a network.
405.2135 Condition: compliance with federal, State, and local laws and regulations.
405.2136 Condition: governing body and management.
405.2137 Condition: patent long-term program and patient care plan.
405.2138 Condition: patients' rights and responsibilities.
405.2139 Condition: medical records.
405.2140 Condition: physical environment.
405.2160 Condition: affiliation agreement or arrangement.
405.2161 Condition: director of a renal dialysis facility or renal dialysis center.
405.2162 Condition: staff of a renal dialysis facility or renal dialysis center.
405.2163 Condition: minimal service requirements for a renal dialysis facility or renal dialysis center.
405.2170 Condition: director of a renal transplantation center.
405.2171 Condition: minimal service requirements for a renal transplantation center.

APPENDIX: End-Stage Renal Disease Network Areas.

Subpart U—Conditions for Coverage of Suppliers of End Stage Renal Disease (ESRD) Services

§ 405.2100 Scope of subpart.

(a) The regulations in this subpart prescribe the role which End-Stage Renal Disease (ESRD) networks will have in the ESRD program, establish the mechanism by which minimal utilization rates pursuant to section 226(g) of the Social Security Act (42 U.S.C. 426(g)) will be promulgated and applied, and describe the health and safety requirements that facilities furnishing ESRD care to beneficiaries must meet. These regulations further prescribe the role of ESRD networks in providing the medical review requirements of section 226(g) prior to and following the establishment of Professional Standards Review Organizations under Part B of Title XI of the Social Security Act (42 U.S.C. 1320c et. seq.).

(b) The general objectives of the ESRD program are contained in § 405.2101, and general definitions are contained in § 405.2102. The provisions of §§ 405.2110–405.2114 discuss the establishment and activities of ESRD Networks, the Network Coordinating Councils, and the Medical Review Boards. Sections 405.2120–405.2124 discuss the establishment of minimal utilization rates and the requirements for approval of facilities with respect to such rates. Sections 405.2130–405.2140 discuss general requirements for, and description of, all facilities furnishing ESRD services. Sections 405.2160–405.2163 discuss specific requirements for facilities which furnish ESRD dialysis services. Sections 405.2170 and 405.2171 discuss specific requirements for facilities which furnish ESRD transplantation services.

(c) The provisions of this subpart are effective 90 days following date of publication. Notwithstanding such effective date, the provisions of the interim regulations in §§ 405.116(g), 405.231(g) and (h), and the Appendix to Subpart B of this part shall continue in effect for a period not to exceed 12 months following such effective date, for the limited purpose of assuring an orderly transition from such interim regulations to the provisions of this subpart and, in particular, so that facilities approved under the ESRD program pursuant to such interim regulations which do not also qualify for continued approval under the terms of this subpart, may be phased out of the Medicare program in a manner that will minimize disruption of services to ESRD patients. However, (1) beginning with the effective date of these regulations, no new applications for exceptions under the interim regulations (§ 405.116(g), 405.231 (g) and (h), and the Appendix to Subpart B of this part) will be accepted; and (2) beginning 6 months after such effective date: (i) no further exceptions will be granted under the interim regulations (§§ 405.116(g), 405.231(g) and (h), and the Appendix to Subpart B of this part); and (ii) determinations with respect to a facility's approval or nonapproval for reimbursement under this subpart will supersede determinations made under such interim regulations.

(d) A facility previously participating under the interim regulations will not be approved under the program established by Subpart U until it has demonstrated that it meets all the applicable requirements of this Subpart, including the appropriate minimal utilization rate. It may continue under the interim program only for a period not to exceed 1 year from the effective date of these amendments (see § 405.2100(c) of this part). During this period it may demonstrate its ability to meet the appropriate minimal utilization rate. Failure to qualify under this Subpart will automatically terminate coverage of such facility's services under the ESRD program at the end of such year.

§ 405.2101 Objectives of the end-stage renal disease (ESRD) program.

The objectives of the end-stage renal disease program are:

(a) To assist beneficiaries who have been diagnosed as having end-stage renal disease (ESRD) to receive the care they need;

(b) To encourage proper distribution and effective utilization of ESRD treatment resources while maintaining or improving the quality of care; and

(c) To provide the flexibility necessary for the efficient delivery of appropriate care by physicians and facilities.

§ 405.2102 Definitions.

As used in this subpart, the following definitions apply:

(a) *Agreement.* The ESRD facility has an agreement whereby another facility assumes responsibility for furnishing certain services to patients and for obtaining reimbursement for such services.

(b) *Arrangement.* The ESRD facility arranges for another facility to furnish certain services to patients but assumes responsibility for such services and for obtaining reimbursement therefor.

(c) *Dialysis.* A process by which dissolved substances are removed from a patient's body by diffusion from one fluid compartment to another across a semipermeable membrane. The two types of dialysis which are currently in common clinical practice are hemodialysis and peritoneal dialysis.

(d) *End-Stage Renal Disease (ESRD).* That stage of renal impairment which is virtually always irreversible and permanent and requires dialysis or kidney transplantation to ameliorate uremic symptoms and maintain life.

(e) *ESRD facility.* A facility which is approved to furnish at least one specific ESRD service (see § 405.2102(f)). Such facilities are:

(1) *Renal Transplantation Center.* A hospital unit which is approved to furnish directly transplantation and other medical and surgical specialty services required for the care of the ESRD transplant patients, including inpatient dialysis furnished directly or under arrangement. A Renal Transplantation Center may also be a Renal Dialysis Center.

(2) *Renal dialysis center.* A hospital unit which is approved to furnish the full spectrum of diagnostic, therapeutic (including inpatient dialysis furnished directly or under arrangement), and rehabilitative services, except renal transplantation required for the care of ESRD dialysis patients.

(3) *Renal dialysis facility.* A unit which is approved to furnish dialysis service(s) to ESRD patients.

(f) *ESRD service.* The type of care or services furnished to an ESRD patient. Such types of care are:

(1) *Transplantation service.* A process
y which (a) a kidney is excised from a
ive or cadaveric donor, (b) such kidney
s implanted in an ESRD patient, and
c) supportive care is furnished to the
iving donor and to the recipient follow-
ng implantation.

(2) *Dialysis service:*

(i) *Chronic maintenance dialysis.* Di-
lysis which is regularly furnished on an
utpatient basis to an ESRD patient (at
ny level of patient involvement) in
ither a hospital-based or nonhospital-
ased setting;

(ii) *Inpatient dialysis.* Dialysis which,
ecause of medical necessity, is furnished
an ESRD patient on a temporary in-
atient basis in a hospital; or

(iii) *Self-care dialysis training.* A pro-
am which trains ESRD patients or
eir helpers, or both, to perform self-
re dialysis.

(g) *Furnishes Directly.* The ESRD
cility provides the service through its
n staff and employees, or through
dividuals who are under direct contract
furnish such services personally for
e facility (i.e., not through "agree-
ents" or "arrangements").

(h) *Furnishes on the Premises.* The
RD facility furnishes services on its
ain premises; or on its other premises
at are: (1) contiguous with or in im-
diate proximity to the main premises;
d, (2) under the direction of the same
ofessional staff and governing body as
main premises.

i) *Histocompatibility testing.* Labora-
y test procedures which determine
mpatibility between a potential donor
an and a potential organ transplant
ipient.

j) *Medical Care Criteria.* Predeter-
ned elements against which aspects of
quality of a medical service may be
pared. They are developed by pro-
sionals relying on professional ex-
tise and on the professional literature.

k) *Medical Care Norms.* Numerical or
istical measures of usual observed
formance. Norms are derived from
regate information related to the
lth care provided to a large number
atients over a period of time.

) *Medical Care Standards.* Profes-
ally developed expressions of the
ge of acceptable variation from a
n or criterion.

n) *Medical care evaluation study*
E). Review of health care services,
lly performed retrospectively, in
h an indepth assessment of the
ity and/or utilization of such serv-
is made.

) *Network, ESRD.* An approved or-
zed group of ESRD facilities in a
gnated geographic area which by
r type and location, and because of
l referral patterns, collectively fur-
s the necessary care for ESRD pa-
s in the population served.

) *Network Coordinating Council.*
referred to as "Council"). A group
presentatives of all the ESRD facili-
in a network which acts as an ad-
strative governing body to the net-
, as a resource to community health
ners, and as a liaison to the Federal
rnment.

(p) *Organ procurement.* The process of acquiring donor kidneys. (See item (q) in this section.)

(q) *Organ procurement agency.* An organization which performs, or coordinates the performance of, all the following services:

(1) Harvesting of donated kidneys;

(2) Preservation of donated kidneys;

(3) Transportation of donated kidneys; and

(4) Maintenance of a system to locate prospective recipients for harvested organs.

(r) *Personnel (qualified), ESRD:* (1) *Chief executive officer (qualified).* A person who: (i) Holds at least a baccalaureate degree or its equivalent and has at least 1 year of experience in an ESRD unit; or

(ii) Is a qualified registered nurse or qualified physician director pursuant to paragraphs (4) and (5) of this item (r); or

(iii) As of the effective date of these regulations, has demonstrated capability by acting for at least 2 years as a chief executive officer in a dialysis unit or transplantation program.

(2) *Dietitian (qualified).* A person who: (i) Is eligible for registration by the American Dietetic Association under its requirements in effect on the publication of these regulations, and has at least 1 year of experience in clinical nutrition; or

(ii) Has a baccalaureate or advanced degree with major studies in food and nutrition or dietetics, and has at least 1 year of experience in clinical nutrition.

(3) *Medical Record Practitioner (Qualified).* A person who:

(i) Has graduated from a program for Medical Record Administrators accredited by the Council on Medical Education of the American Medical Association and the American Medical Record Association, and is eligible for certification as a Registered Record Administrator (RRA) by the American Medical Record Association under its requirements in effect on the publication of these regulations; or

(ii) Has graduated from a program for Medical Record Technicians approved jointly by the Council on Medical Education of the American Medical Association and the American Medical Record Association, and is eligible for certification as an Accredited Record Technician (ART) by the American Medical Record Association under its requirements in effect on the publication of these regulations; or

(iii) Has successfully completed and received a satisfactory grade in the American Medical Record Association's Correspondence Course for Medical Record Personnel approved by the Accrediting Commission of the National Home Study Council, and is eligible for certification as an Accredited Record Technician by the American Medical Record Association under its requirements in effect on the publication of these regulations.

(4) *Nurse Responsible for Nursing Service (Qualified).* A person who is licensed as a registered nurse by the State in which practicing, and (i) Has at least 12 months of experience in clinical nursing, and an additional 6 months of experience in nursing care of the patient with permanent kidney failure or undergoing kidney transplantation, including training in and experience with the dialysis process; or

(ii) Has 18 months of experience in nursing care of the patient on maintenance dialysis, or in nursing care of the patient with a kidney transplant, including training in and experience with the dialysis process.

(iii) If the nurse responsible for nursing service (qualified) is in charge of self-care dialysis training, at least 3 months of the total required ESRD experience is in training patients in self-care.

(5) *Physician-Director (Qualified).* A physician (see section 1861(r)(1) of the Act) who:

(i) Is board eligible or board certified in internal medicine or pediatrics by a professional board, and has had at least 12 months of experience or training in the care of patients at ESRD facilities; or

(ii) During the 5-year period prior to the effective date of these regulations, served for at least 12 months as director of a dialysis or transplantation program.

(iii) In those areas where a qualified physician is not available to direct a participating dialysis facility, another physician (see section 1861(r)(1) of the Act) may direct the facility, subject to the approval of the Secretary.

(6) *Social Worker (Qualified).* A person who is licensed, if applicable, by the State in which practicing, and

(i) Has completed a course of study with specialization in clinical practice at, and holds a masters degree from, a graduate school of social work accredited by the Council on Social Work Education; or

(ii) Has served for at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to the effective date of these regulations, and has established a consultative relationship with a social worker who qualifies under item (6)(i) of this section.

(7) *Transplantation Surgeon (Qualified).* A person who:

(i) Is board eligible or board certified in general surgery or urology by a professional board; and

(ii) Has at least 12 months training or experience in the performance of renal transplantation and the care of patients with renal transplants.

§ 405.2110 Designation of ESRD network areas.

(a) The Secretary designates ESRD network areas, each serving a minimum population base of 3.5 million and each including at least two renal transplant centers, and is publishing notice thereof as an appendix to this subpart. The Secretary may designate network areas of less than 3.5 million population or a single renal transplant center when necessary for the achievement of the ESRD program objectives (see § 405.2101).

(b) A network area may cross State and HEW Regional boundaries and, to the greatest extent practicable, will be coterminous with Health Service Areas and PSRO areas. The designation of network areas does not imply that the design of the areas will remain static. Network areas may be changed from time to time by publication of amendments to these regulations so that the designations are in accordance with program experience and changing needs.

(c) Network areas are designated for the purpose of geographically describing the location of groups of ESRD facilities which share a collective responsibility to provide access to the various levels and treatment modalities of ESRD care. The designation of network areas does not require a patient to seek access to care only through the facilities in the designated network area in which the patient resides, nor does the designation of network areas preclude patient choice of physicians or facilities or patient referral by physicians to a facility in another designated network area.

§ 405.2111 Designation of network coordinating councils.

(a) With respect to each designated network area, the Secretary will, after he determines that the criteria listed below are met, designate a network coordinating council. The criteria are:

(1) Each certified ESRD facility in the designated network area has been requested to furnish a network coordinating council designated representative from one of the categories listed in paragraph (a)(3) of this section.

(2) At least 75 percent of the certified ESRD facilities in the network area have furnished a designated representative to the network coordinating council.

(3) If not included in such representatives, the council has appointed the following members from within the network:

(i) Transplant surgeon (see § 405.2102 (r)(7)).

(ii) Internist-nephrologist.

(iii) Pediatrician (pediatric nephrologist when available).

(iv) Chief executive officer of an ESRD facility (see § 405.2102(r)(1)).

(v) Qualified dietitian (see § 405.2102 (r)(2)).

(vi) Qualified nurse (see § 405.2102 (r)(4)).

(vii) Qualified social worker (see § 405.2102(r)(6)).

(viii) Dialysis technician.

(ix) Three informed consumers.

(x) Director of a histocompatibility testing laboratory, when available (see § 405.1314(b)(13)).

(xi) Representative of an organ procurement agency, when available.

(b) Initial functions of a network coordinating council. The initial functions of a network coordinating council include at least the following:

(1) If composed of more than 20 persons, appoints an executive committee of 20 or less persons which carries out the activities of the council between meetings of the council.

(2) Elects an executive committee in each succeeding year, which is representative of the constituency of the network and consists of at least 25 percent nonphysicians.

(3) Provides a plan for establishing working relationships with: (i) contiguous ESRD network coordinating councils; (ii) established Professional Standards Review Organizations (PSROs) established under Part B of title XI of the Social Security Act; and, (iii) Health Systems Agencies (HSAs) and State Health Coordinating Councils (SHCCs) established pursuant to the Public Health Service Act as amended by the National Health Planning Resources and Development Act of 1974, P.L. 93–641, which have designated areas that are wholly or in part included in the ESRD network area.

(4) Provides a listing of the network's component facilities, the name(s) of the facility representative(s) to the council and the disciplines they represent, the name(s) of council member(s) other than those representing facilities and the membership category they represent, the ESRD services each facility provides, and a quantitative estimate of each facility's capacity to deliver each service.

(5) Provides signed agreements between itself and each member facility concerning the latter's willingness to participate in council activities.

(6) Appoints a medical review board (see § 405.2113).

(7) Describes a mechanism for the development of procedures for the review of ESRD care (including a mechanism for the development of criteria and standards) under which an established medical review board can operate.

(8) Provides information concerning the current and projected need for ESRD services within the network area to assist the Secretary in making determinations concerning the certification of ESRD facilities within the network area.

(9) Develops network rules of governance including but not limited to the frequency and type of meetings of the network coordinating council, and the medical review board, the executive committee, quorum of these meetings, etc.

§ 405.2112 Designation of ESRD networks.

An ESRD network exists when the member facilities collectively furnish the full spectrum of ESRD care and a designated network coordinating council has begun to function. Within 6 months following the effective date of these regulations, the Secretary will determine whether the requirements for designation of an ESRD network are met.

(a) Criteria for the designation of an ESRD network:

(1) Each certified ESRD facility in the designated area must be permitted to join the network.

(2) The ESRD facilities must execute a membership agreement with the network coordinating council.

(3) Collectively, the member facilities must include the capability for:

(i) Kidney transplantation.

(ii) Inpatient dialysis.

(iii) Chronic maintenance dialysis.

(iv) Self-care dialysis training.

(v) Support services for patients dialyzing themselves at home.

(vi) Organ (kidney) procurement.

(vii) Histocompatibility testing.

(4) A designated network coordinating council has been formed and has begun to function.

(5) The council has established a medical review board which has begun to function to assure, through the application of suitable procedures of health care review, that the services for which payment may be made under the Social Security Act conform to appropriate standards for the provision of health care.

(6) The council has established procedures for utilizing information available from the national ESRD medical information system, and has begun to implement the procedures.

(7) The council has established working relationships with each PSRO and with each designated HSA and SHCC in the network area and with contiguous network coordinating councils.

(b) *Ongoing functions of the network coordinating council in an approved ESRD network.* The ongoing functions of the network coordinating council are performed by the council or the council's executive committee. The network coordinating council performs the following ongoing functions:

(1) Develops a written plan, updated annually, which contains a statement of the network objectives, a method for attaining the network objectives, and a description of the mechanisms to be used for evaluation of progress toward meeting the network objectives.

(2) Submits to the Secretary within 2 months after each calendar year an annual report which contains the following information:

(i) The ESRD services that each facility in the network provides;

(ii) An quantitative estimate of each facility's capacity to deliver each service;

(iii) The anticipated utilization rate for each ESRD service in each facility for each year in the subsequent 3-year period;

(iv) A statement describing reasons for the participation of an ESRD facility reporting utilization rates which do not satisfy the standard(s) for unconditional status (see § 405.2130); and

(v) An overview report on the medical review activities undertaken in the network during the previous year.

(3) Confers with its component ESRD facilities to assist each with the formulation of data for the annual report.

(4) Monitors the functions of the medical review board and provides for the updating as needed of procedures for review, including criteria and standards.

(5) Makes recommendations to member facilities as needed to achieve the objectives of the network.

(6) Continues its working relationships with each PSRO designated in the

work area with respect to the estab-
ment of standards and criteria and
procedures for medical review.
(7) Continues its working relation-
ps with designated HSAs and SHCCs
the network area, assuring working
ationships with respect to information
cerning current and projected needs
ESRD services within the network
a.
(8) Furnishes consultation, as re-
sted by the Medicare intermediary
s) or the appropriate PSRO where it
assumed these review functions, con-
ning the medical necessity of services.
9) Provides information to the Sec-
ary concerning current and projected
lization of network member facilities.
10) Establishes mechanisms to man-
the administrative aspects of its ac-
ties.
11) Establishes mechanisms to man-
the fiscal aspects of its activities.

05.2113 Medical review board.

a) The medical review board consists
a maximum of seven members. The
mbers (with a designated alternate for
h) are appointed by the network co-
inating council. The medical review
rd consists of the following members:
1) An internist actively engaged in
RD care;
2) A qualified transplantation surgeon
ively engaged in ESRD care;
3) A qualified nurse responsible for
sing service;
4) A qualified social worker;
5) One to three additional physi-
n(s) actively engaged in ESRD care.
any area where specialized care (e.g.,
iatric care) is regularly being re-
wed, one of the additional physicians
specialist in that area of care; and
6) In addition, there are available to
medical review board consultants in
cialty areas as needed.
b) No person serving on the medical
iew board has review responsibility
a case in which he has, or had, any
fessional involvement.
c) No person serving on the medical
iew board with a financial interest,
ect or indirect, as defined in § 1155(a)
(B) of the Act, in a facility that
nishes ESRD services may review the
RD services of that facility.
d) The medical review board performs
following functions: (1) Develops a
chanism for monitoring the effective-
s of the patient long-term program
405.2137(a)) in assessing the appro-
ateness of patients for the proposed
atment procedures;
2) Reviews and coordinates the eval-
tion of comparative performance of
ilities and physicians based on ag-
gate data concerning patterns of care
relation to both normative data from
medical information system and cri-
ia and standards developed by the net-
rk for at least the following areas of
tient care: appropriateness of patients
the proposed treatment procedures,
ortality, and morbidity. This review in-
des both physician and nonphysician
rformance;

(3) In concurrence with the network coordinating council, coordinates the performance of medical care evaluation studies within the network, with each ESRD facility participating in at least one but usually more than one medical care evaluation study per year. The medical review board assures that the following tasks are performed for each medical care evaluation study: selection and design of the study, setting criteria and standards, data collection and display, interpretation and analysis of the findings, institution of corrective action, and reperformance of any study which indicates a problem; and

(4) As necessary, performs or delegates the performance of other indepth studies based upon information emanating from paragraphs (d)(1) and (d)(2) of this section, the medical information system, or a perceived need. This includes the coordination and evaluation of individual patient data as necessary for at least the following areas of patient care: appropriateness of patients for the proposed treatment procedures, mortality, and morbidity. This review includes both physician and nonphysician performance.

(e) On the basis of its reviews under paragraph (d) of this section, the medical review board provides, to facilities in the network and to physicians, written recommendations for improvements in the ESRD care of individual patients or groups of patients (or both). If there are facilities in the network, or physicians, that continue to deliver care which the medical review board considers inappropriate or of substandard quality, the medical review board provides all facts concerning this care to the council and to the Secretary.

(f) The medical review board, from time to time but not less than annually, submits to the council and to the Secretary a report on its activities, which includes the following:

(1) The plan of the board for conducting review activities including the process and scheduling of reviews and studies, and the process of information exchange between the board, the council, and the facilities within the network;

(2) Findings of its reviews and studies; and

(3) Recommendations with respect to the more effective accomplishment of the purposes and objectives of the board.

§ 405.2114 Relationship of ESRD networks to health care review organizations and to health service planning organizations.

(a) The network coordinating council develops written working arrangements with Health Systems Agencies and State Health Coordinating Councils whose designated planning area is wholly or in part included in the ESRD network area to assure that these organizations receive appropriate professional advice concerning the need for ESRD facilities and services. These written arrangements describe the procedure(s) by which the council integrates its planning responsibility with the planning responsibilities of the Health Systems Agencies and the State Health Coordinating Councils. With regard to continued planning assistance, the network coordinating council accepts planning responsibility as requested by the Health Systems Agencies and the State Health Coordinating Councils.

(b) The medical review board develops written arrangements with PSROs established under Part B of title XI of this Act whose designated area is wholly or in part included in the ESRD network area to assure that these organizations receive appropriate professional advice concerning the quality of medical services required by and given to ESRD patients. These written arrangements describe the procedures by which the medical review board will integrate its medical review responsibility with the medical review responsibility of the PSROs. These arrangements are designed so as to avoid, to the maximum extent possible, the duplication of activities, and become effective only after the approval of the Secretary. With regard to continued medical review assistance, the medical review board will accept review responsibility as requested by the PSROs.

§ 405.2120 Minimal utilization rates: general.

Section 226(g) of the Social Security Act (42 U.S.C. 426(g)) authorizes the Secretary to limit reimbursement for ESRD care to those facilities which meet such requirements as the Secretary may prescribe, including minimal utilization rates for covered procedures. The minimal utilization rates, which are explained and specified in §§ 405.2121–405.2130, pertain to dialyses and transplantations. These utilization rates may be changed from time to time in accordance with program experience, and such changes will be published as amendments to these regulations.

§ 405.2121 Basis for determining minimal utilization rates.

In developing minimal utilization rates, the Secretary takes into account the performance of ESRD facilities, the availability of care, the quality of care, and the efficient utilization of equipment and personnel, based on the following evidence:

(a) Information obtained from the Network Coordinating Council (see § 405.2112(b)(2)) and other sources covering current rates of utilization in ESRD facilities;

(b) Information on the geographic distribution of ESRD patients and facilities;

(c) Information on quality of care; and

(d) Information on operational and management efficiency.

§ 405.2122 Types and duration of classification according to utilization rates.

An ESRD facility which meets all the other conditions fo rcoverage of ESRD

services will be classified according to its utilization rate(s) as follows: unconditional status, conditional status, exception status, or not eligible for reimbursement for that ESRD service. Such classification will be based on previously reported utilization data (see § 405.2124) and will be effective until notification of subsequent classification occurs.

(a) Unconditional status: Unconditional status will be granted to those ESRD facilities whose utilization rate (as calculated in § 405.2124) meets the rates for unconditional status. Such classification will continue until subsequently calculated statistics or amended minimal utilization require a change.

(b) Conditional status: Conditional status will be granted:

(i) To an ESRD facility whose utilization rate meets the minimal rate for conditional status in § 405.2130; and

(ii) To an ESRD facility which has not previously participated in the ESRD program provided that the ESRD facility submits a written plan which details how it will achieve conditional utilization rates by the conclusion of the first calendar year of its operation under the program and unconditional utilization rates during the third calendar year of operation under the program. Such an ESRD facility will be subject to evaluation of its classification after the close of its first calendar year to ascertain whether the written plan is being properly implemented.

(c) Exception status: A renal dialysis center or a renal dialysis facility meeting neither the unconditional nor conditional minimal utilization rate classification but meeting all other conditions for coverage under this subpart may be approved for a time limited exception status by the Secretary providing the facility is located in an area lacking a sufficient population base of support in addition to insufficient numbers of patients to meet the rate and the facility's absence would adversely affect the achievement of ESRD program objectives.

§ 405.2123 Reporting of utilization rates for initial classification.

(a) Within 3 months after the effective date of this subpart, each facility furnishing ESRD services under the interim ESRD regulations or a new applicant facility will submit to the Secretary a report on its utilization rates which will include the following:

(1) Each hospital furnishing renal transplantation service will report both the number of transplants performed during the most recent year of operation and the number performed during each of the preceding 2 calendar years.

(2) Each hospital or nonhospital facility furnishing dialysis service will report the number of dialysis stations it had operating and the total number of dialyses performed during both the most recent year of operation and each of the preceding 2 calendar years.

(b) For the purposes of this report, all dialyses performed (both inpatient and outpatient) and all dialysis stations in operation during the reporting period will be included. Self-care dialysis training stations which were utilized to successfully train at least six self dialysis patients per station per calendar year will be reported but may be excluded from the calculation of utilization rates. The dialyses performed on any such self-care dialysis training stations will also be excluded in the calculation of facility utilization rates.

§ 405.2124 Calculation of utilization rates for comparison with minimal utilization rate(s) and notification of status.

For purposes of classification the Secretary will use either the utilization rate for the preceding 12 months or the average utilization rate of the preceding 2 calendar years, whichever is higher. The Secretary will inform each ESRD facility and the network coordinating council of the network area in which the ESRD facility is located of the results of this classification.

§ 405.2130 Condition: Minimal utilization rates.

The ESRD facility meets the applicable minimal utilization rate(s) indicated below for unconditional or conditional status, unless granted exception status in accordance with § 405.2122(c):

(a) *Standard: Renal Transplantation Center.*

(1) Unconditional status: 15 or more transplants performed annually.

(2) Conditional status: 7 to 14 transplants performed annually.

(b) *Standard: Dialysis facilities or centers performing greater than 20 percent of their dialyses on outpatients.*

(1) For any facility located within a standard metropolitan statistical area of 500,000 population or greater:

(i) Unconditional status—6 or more dialysis stations with performance of an average of 4.5 or more dialyses per station per week;

(ii) Conditional status—6 or more dialysis stations with performance of an average of between 4.0 and 4.5 dialyses per station per week; or 4 or 5 dialysis stations with performance of an average of 4.5 or more dialyses per station per week.

(2) For any facility located in a standard metropolitan statistical area of less than 500,000 population, or in an area not included in a standard metropolitan statistical area:

(i) Unconditional status—3 or more dialysis stations with performance of an average of 4.0 or more dialyses per station per week;

(ii) Conditional status—2 dialysis stations with performance of an average of 4.0 or more dialyses per station per week.

(c) *Standard: Renal dialysis centers performing 20 percent or less of their dialyses on outpatients:* (1) Unconditional status—3 or more dialysis stations with performance of an average of 4.0 or more dialyses per station per week;

(2) Conditional status—2 dialysis stations with performance of an average of 4.0 or more dialyses per station per week.

§ 405.2131 Condition: Provider status: renal transplantation center or renal dialysis center.

A renal transplantation center or a renal dialysis center (§ 405.2102(e) (1) or (2)) operated by a hospital may qualify for approval and be reimbursed under the ESRD program only if the hospital is otherwise an approved provider in the Medicare program.

§ 405.2132 Condition: fulfillment of service needs in network.

The ESRD facility, or an expansion of the renal dialysis center or facility's capacity, is needed to increase the available ESRD services which would otherwise be inadequate for the network area. The facility furnishes evidence in support of its request for approval showing that:

(a) There are ESRD patients in the network area for whom the proposed services of the facility are needed;

(b) These patients cannot be expected to receive appropriate therapy from another ESRD treatment facility in the network area; and

(c) The facility is qualified to furnish the proposed services.

§ 405.2133 Condition: furnishing data and information for ESRD program administration.

The ESRD facility, laboratory performing histocompatibility testing, and organ procurement agency furnishes data and information in the manner and at the intervals specified by the Secretary, pertaining to its ESRD patient care activities and costs, for inclusion in a national ESRD medical information system and in compilations relevant to program administration, including claims processing and reimbursement. Such information is treated as confidential when it pertains to individual patients and is not disclosed except as authorized by Department regulations on confidentiality and disclosure (see 45 CFR Part 5, 5b, and 20 CFR Parts 401 and 422 (Subpart E)).

§ 405.2134 Condition: Membership in a network.

Six months after the effective date of this subpart, the ESRD facility must have executed a membership agreement with an approved network and must be providing acceptable representation to the Network Council.

(a) *Standard: membership agreement.* The membership agreement is signed by an authorized individual on behalf of the facility, providing for the facility's participation in Council activities and medical care evaluation studies (see § 405.2113 (d)(3)).

(b) *Standard: representation.* The facility appoints at least one representative to the Council and more than one representative, when necessary, (§ 405.2111), for proper administration of the Network's general program functions.

05.2135 Condition: compliance with Federal, State and local laws and regulations.

he ESRD facility is in compliance n applicable Federal, State and local as, and regulations.

a) *Standard: licensure.* Where State applicable local law provides for the nsing of ESRD facilities, the facility s

1) Licensed pursuant to such law; or

2) Approved by the agency of such te or locality responsible for such li- esing as meeting the standards estab- ed for such licensing.

b) *Standard: licensure or registration personnel.* Each staff member is cur- etly licensed or registered in accord- e with applicable law.

c) *Standard: conformity with other as.* The facility is in conformity with licable laws and regulations pertain- n to fire safety, equipment, and other vant health and safety requirements.

05.2136 Condition: governing body and management.

he ESRD facility is under the con- r of an identifiable governing body, or gnated person(s) so functioning, n full legal authority and responsibil- for the governance and operation of facility. The governing body adopts enforces rules and regulations rela- to its own governance and to the lth care and safety of patients, to the tection of the patients' personal and perty rights, and to the general oper- on of the facility. The governing body eives and acts upon recommendations communications from the Medical iew Board and the Network Coordi- ing Council. The governing body ap- nts a chief executive officer who is re- nsible for the overall management of facility.

a) *Standard: disclosure of ownership.* ESRD facility supplies full and plete information to the State sur- agency (§ 405.1902(a)) as to the ntity of: (1) each person who has any ect or indirect ownership interest of per centum or more in the facility, or is the owner (in whole or in part) of mortgage, deed of trust, note, or er obligation secured (in whole or in t) by the facility or any of the prop- or assets of the facility; (2) each cer and director of the corporation, if facility is organized as a corporation; (3) each partner, if the facility is anized as a partnership; and promptly orts to the State survey agency any nges which would affect the current uracy of the information so required e supplied.

b) *Standard: operational objectives.* e operational objectives of the ESRD ility, including the services that it vides, are established by the govern- body and delineated in writing.

The governing body adopts effective ninistrative rules and regulations at are designed to safeguard the health l safety of patients and to govern the eral operations of the facility, in ac- dance with legal requirements. Such rules and regulations are in writing and dated. The governing body ensures that they are operational, and that they are reviewed at least annually and revised as necessary.

(1) The objectives of the facility are formulated in writing and clearly stated in documents appropriate for distribution to patients, facility personnel, and the public.

(2) A description of the services provided by the facility, together with a categorical listing of the types of diagnostic and therapeutic procedures that may be performed, is readily available upon request to all concerned.

(3) Admission criteria are adopted by the facility and are readily available to ensure equitable access to such service.

(4) The operational objectives and administrative rules and regulations of the facility are reviewed at least annually and revised as necessary by the administrative staff, medical director, and other appropriate personnel of the facility, and are adopted when approved by the governing body.

(5) There is a written requirement that the governing body receive all recommendations and communications from the Medical Review Board and the Network Coordinating Council and appropriately act on such recommendations and communications.

(c) *Standard: chief executive officer.* The governing body appoints a qualified chief executive officer who, as the ESRD facility's administrator: is responsible for the overall management of the facility; enforces the rules and regulations relative to the level of health care and safety of patients, and to the protection of their personal and property rights; and plans, organizes, and directs those responsibilities delegated to him by the governing body. Through meetings and periodic reports, the chief executive officer maintains on-going liaison among the governing body, medical and nursing personnel, and other professional and supervisory staff of the facility, and acts upon recommendations made by the medical staff, the governing body, and the Medical Review Board. In the absence of the chief executive officer, a qualified person is authorized in writing to act on the officer's behalf.

(1) The governing body delineates in writing the responsibilities of the chief executive officer, and ensures that he/she is sufficiently free from other duties to provide effective direction and management of the operations and fiscal affairs of the facility.

(2) The chief executive officer serves on a full-time or part-time basis, in accordance with the scope of the facility's operations and administrative needs, and devotes sufficient time to the conduct of such responsibilities.

(3) The responsibilities of the chief executive officer include but are not limited to:

(i) Implementing the policies of the facility and coordinating the provision of services, in accordance with delegations by the governing body.

(ii) Organizing and coordinating the administrative functions of the facility, redelegating duties as authorized, and establishing formal means of accountability for those involved in patient care.

(iii) Authorizing expenditures in accordance with established policies and procedures.

(iv) Familiarizing the staff with the facility's policies, rules, and regulations, and with applicable Federal, State, and local laws and regulations.

(v) Maintaining and submitting such records and reports, including a chronological record of services provided to patients, as may be required by the facility's internal committees and governing body, the Medical Review Board (§ 405.2113), or as required by the Secretary.

(vi) Participating in the development, negotiation, and implementation of agreements or contracts into which the facility may enter, including network agreements, (§ 405.2134), subject to approval by the governing body of such agreements or contracts.

(vii) Participating in the development of the organizational plan and ensuring the development and implementation of an accounting and reporting system, including annual development of a detailed budgetary program, maintenance of fiscal records, and quarterly submission to the governing body of reports of expenses and revenues generated through the facility's operation.

(viii) Ensuring that the facility employs the number of qualified personnel needed; that all employees have appropriate orientation to the facility and their work responsibilities upon employment; and that they have an opportunity for continuing education and related development activities.

(d) *Standard: personnel policies and procedures.* The governing body, through the chief executive officer of the ESRD facility, is responsible for maintaining and implementing written personnel policies and procedures that support sound patient care and promote good personnel practices. These policies and procedures ensure that:

(1) All members of the facility's staff are qualified to perform the duties and responsibilities assigned to them and meet such Federal, State, and local professional requirements as may apply.

(2) A safe and sanitary environment for patients and personnel exists, and reports of incidents and accidents to patients and personnel are reviewed to identify health and safety hazards. Health supervision of personnel is provided, and they are referred for periodic health examinations and treatments as necessary or as required by Federal, State, and local laws. Procedures are established for routine testing to ensure detection of hepatitis and other infectious diseases.

(3) If the services of trainees are utilized in providing ESRD services, such trainees are under the direct supervision of qualified professional personnel.

(4) Complete personnel records are maintained on all personnel. These include health status reports, resumes of training and experience, and current job descriptions that reflect the employees' responsibilities and work assignments.

(5) Personnel policies are written and made available to all personnel in the facility. The policies provide for an effective mechanism to handle personnel grievances.

(6) All personnel of the facility participate in educational programs on a regular basis. These programs cover initial orientation, and continuing inservice training, including procedures for infection control. Records are maintained showing the content of training sessions and the attendance at such sessions.

(7) Personnel manuals are maintained, periodically updated, and made available to all personnel involved in patient care.

(e) *Standard: use of outside resources.* If the ESRD facility makes arrangements for the provision of a specific service as authorized in this subpart, the responsibilities, functions, objectives, and the terms of each arrangement, including financial provisions and charges, are delineated in a document signed by an authorized representative of the facility and the person or agency providing the service. The chief executive officer when utilizing outside resource, as a consultant, assures that he is apprised of recommendations, plans for implementation, and continuing assessment through dated, signed reports, which are retained by the chief executive officer for follow-up action and evaluation of performance.

(f) *Standard: patient care policies.* The ESRD facility has written policies, approved by the governing body, concerning the provision of dialysis and other ESRD services to patients. The governing body reviews implementation of policies periodically to ensure that the intent of the policies is carried out. These policies are developed by the physician responsible for supervising and directing the provision of ESRD services, or the facility's organized medical staff (if there is one), with the advice of (and with provision for review of such policies from time to time, but at least annually, by) a group of professional personnel associated with the facility, including, but not limited to, one or more physicians and one or more registered nurses experienced in rendering ESRD care.

(1) The patient care policies cover the following:

(i) Scope of services provided by the facility (either directly or under arrangement).

(ii) Admission and discharge policies (in relation to both in-facility care and self-care or home care).

(iii) Medical supervision and physician services.

(iv) Patient long term programs, patient care plans and methods of implementation.

(v) Care of patients in medical and other emergencies.

(vi) Pharmaceutical services.

(vii) Medical records (including those maintained in the ESRD facility and in the patients' homes, to ensure continuity of care).

(viii) Administrative records.

(ix) Use and maintenance of the physical plant and equipment.

(x) Consultant qualifications, functions, and responsibilities.

(xi) Surveillance of home adaptation if the facility has responsibility for home dialysis patients.

(2) The physician-director of the facility is designated in writing to be responsible for the execution of patient care policies. If the responsibility for day-to-day execution of patient care policies has been delegated by a physician director to a registered nurse, the physician-director provides medical guidance to the nurse in such matters.

(3) The facility policy provides that, whenever feasible, hours for dialysis are scheduled for patient convenience and that arrangements are made to accommodate employed patients who wish to be dialyzed during their non-working hours.

(4) The governing body adopts policies to ensure there is evaluation of the progress each patient is making toward the goals stated in the patient's long term program and patient's care plan (see § 405.2137(a)). Such evaluations are carried out through regularly scheduled conferences, with participation by the staff involved in the patient's care.

(g) *Standard: medical supervision and emergency coverage.* The governing body of the ESRD dialysis and/or transplant facility ensures that the health care of every patient is under the continuing supervision of a physician and that a physician is available in emergency situations.

(1) The physician responsible for the patient's medical supervision evaluates the patient's immediate and long-term needs and on this basis prescribes a planned regimen of care which covers indicated dialysis and other ESRD treatments, services, medications, diet, special procedures recommended for the health and safety of the patient, and plans for continuing care and discharge. Such plans are made with input from other professional personnel involved in the care of the patient.

(2) The governing body ensures that there is always available medical care for emergencies, 24 hours a day, 7 days a week. There is posted at the nursing/monitoring station a roster with the names of the physicians to be called, when they are available for emergencies, and how they can be reached.

(h) *Standard: medical staff.* The governing body of the ESRD facility designates a qualified physician (see § 405.2102(r)(5) as director of the ESRD services; the appointment is made upon the recommendation of the facility's organized medical staff, if there is one. The governing body establishes written policies regarding the development, negotiation, consummation, evaluation, and termination of appointments to the medical staff.

§ 405.2137 Condition: patient long-term program and patient care plan.

Each facility maintains for each patient a written long-term program and a written patient care plan to ensure that each patient receives the appropriate modality of care and the appropriate care within that modality. The patient, or where appropriate, parent or legal guardian is involved with the health team in the planning of care. A copy of the current program and plan accompany the patient on interfacility transfer.

(a) *Standard: patient long-term program.* There is a written long-term program representing the selection of a suitable treatment modality (i.e., dialysis or transplantation) and dialysis setting (e.g., home, self care) for each patient.

(1) The program is developed by a professional team which includes but is not limited to the physician director of the dialysis facility or center where the patient is currently being treated, a physician director of a center or facility which offers self-care dialysis training (if not available at the location where the patient is being treated), a transplant surgeon, a qualified nurse responsible for nursing services, a qualified dietitian and a qualified social worker.

(2) The program is formally reviewed and revised in writing as necessary by a team which includes but is not limited to the physician director of the dialysis facility or center where the patient is presently being treated, in addition to the other personnel listed in paragraph (a)(1) of this section at least every 12 months or more often as indicated by the patient's response to treatment (see § 405.2161(b)(1) and § 405.2170(a)).

(3) The patient, parent, or legal guardian, as appropriate, is involved in the development of the patient's long-term program, and due consideration is given to his preferences.

(4) A copy of the patient's long-term program accompanies the patient on interfacility transfer or is sent within 1 working day.

(b) *Standard: patient care plan.* There is a written patient care plan for each patient of an ESRD facility based upon the nature of the patient's illness, the treatment prescribed, and an assessment of the patient's needs.

(1) The patient care plan is personalized for the individual, reflects the psychological, social, and functional needs of the patient, and indicates the ESRD and other care required as well as the individualized modifications in approach necessary to achieve the long-term and short-term goals.

(2) The plan is developed by a professional team consisting of at least the physician responsible for the patient's ESRD care, a qualified nurse responsible for nursing services, a qualified social worker, and a qualified dietitian.

(3) The patient, parent, or legal guardian, as appropriate, is involved in the development of the care plan, and due consideration is given to his preferences.

(4) Although care is evaluated and updated continuously, the care plan is reviewed by the team at least monthly and revised as necessary to ensure that it provides for the ongoing needs of the patient. A coordinator from the team is appointed by the physician. The coordinator ensures that conferences are convened to review the patient care plan, and that changes are recorded and progress notes incorporated into the patient's record.

(5) The patient care plan accompanies the patient upon interfacility transfer or is sent within 1 working day.

§ 405.2138 Condition: patients' rights and responsibilities.

The governing body of the ESRD facility adopts written policies regarding the rights and responsibilities of patients and, through the chief executive officer, is responsible for development of, and adherence to, procedures implementing such policies. These policies and procedures are made available to patients and any guardians, next of kin, sponsoring agency(ies), representative payees (selected pursuant to section 205(j) of the Social Security Act and Subpart Q of Part 404 of this Chapter), and to the public. The staff of the facility is trained and involved in the execution of such policies and procedures. The patients' rights policies and procedures ensure at least the following:

(a) *Standard: informed patients.* All patients in the facility:

(1) Are fully informed of these rights and responsibilities, and of all rules and regulations governing patient conduct and responsibilities,

(2) Are fully informed of services available in the facility and of related charges including any charges for services not covered under title XVIII of the Social Security Act;

(3) Are fully informed by a physician of their medical condition unless medically contraindicated (as documented in their medical records).

(b) *Standard: participation in planning.* All patients treated in the facility:

(1) Are afforded the opportunity to participate in the planning of their medical treatment and to refuse to participate in experimental research;

(2) Are transferred or discharged only for medical reasons or for the patient's welfare or that of other patients, or for nonpayment of fees (except as prohibited by title XVIII of the Social Security Act), and are given advance notice to ensure orderly transfer or discharge.

(c) *Standard: respect and dignity.* All patients are treated with consideration, respect, and full recognition of their individuality and personal needs, including the need for privacy in treatment. Provision is made for translators where a significant number of patients exhibit language barriers.

(d) *Standard: confidentiality.* All patients are ensured confidential treatment of their personal and medical records, and may approve or refuse release of such records to any individual outside the facility, except in case of their transfer to another health care institution or as required by Federal, State, or local law and the Secretary for proper administration of the program.

(e) *Standard: grievance mechanism.* All patients are encouraged and assisted to understand and exercise their rights. Grievances and recommended changes in policies and services may be addressed to facility staff, administration, the Network Council, and agencies or regulatory bodies with jurisdiction over the facility, through any representative of the patient's choice, without restraint or interference, and without fear of discrimination or reprisal.

§ 405.2139 Condition: medical records.

The ESRD facility maintains complete medical records on all patients (i.e., those receiving care within the facility and those self-care or home dialysis patients for whom the facility has assumed responsibility) in accordance with accepted professional standards and practices. A member of the facility's staff is designated to serve as supervisor of medical records services, and ensures that all records are properly documented, completed, and preserved. The medical records are completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information.

(a) *Standard: medical record.* Each patient's medical record contains sufficient information to identify the patient clearly, to justify the diagnosis and treatment, and to document the results accurately. All medical records contain the following general categories of information: Documented evidence of assessment of the needs of the patient, of establishment of an appropriate plan of treatment, and of the care and services provided (see § 405.2137 (a) and (b)); identification and social data; signed consent forms; referral information with authentication of diagnosis; medical and nursing history of patient; report(s) of physician examination(s); diagnostic and therapeutic orders, observations, and progress notes; reports of treatments and clinical findings; reports of laboratory and other diagnostic tests and procedures; and discharge summary including final diagnosis and prognosis.

(b) *Standard: protection of medical record information.* The ESRD facility safeguards medical record information against loss, destruction, or unauthorized use. The ESRD facility has written policies and procedures which govern the use and release of information contained in medical records. Written consent of the patient, or of an authorized person acting in behalf of the patient, is required for release of information not provided by law. Medical records are made available under stipulation of confidentiality for inspection by authorized agents of the Secretary, as required for administration of the ESRD program under Medicare.

(c) *Standard: medical records supervisor.* A member of the ESRD facility's staff is designated to serve as supervisor of the facility's medical records service. The functions of the medical records supervisor include, but are not limited to, the following: Ensuring that the records are documented, completed, and maintained in accordance with accepted professional standards and practices; safeguarding the confidentiality of the records in accordance with established policy and legal requirements; ensuring that the records contain pertinent medical information and are filed for easy retrieval. When necessary, consultation is secured from a qualified medical record practitioner.

(d) *Standard: Completion of medical records and centralization of clinical information.* Current medical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient's medical record.

(e) *Standard: retention and preservation of records.* Medical records are retained for a period of time not less than that determined by the State statute governing records retention or statute of limitations; or in the absence of a State statute, 5 years from the date of discharge; or, in the case of a minor, 3 years after the patient becomes of age under State law, whichever is longest.

(f) *Standard: location and facilities.* The facility maintains adequate facilities, equipment, and space conveniently located, to provide efficient processing of medical records (e.g., reviewing, filing, and prompt retrieval) and statistical medical information (e.g., required abstracts, reports, etc.).

(g) *Standard: transfer of medical information.* The facility provides for the interchange of medical and other information necessary or useful in the care and treatment of patients transferred between treating facilities, or in determining whether such patients can be adequately cared for otherwise than in either of such facilities.

§ 405.2140 Condition: physical environment.

The physical environment in which ESRD services are furnished affords a functional, sanitary, safe, and comfortable setting for patients, staff, and the public.

(a) *Standard: building and equipment.* The physical structure in which ESRD services are furnished is constructed, equipped, and maintained to insure the safety of patients, staff, and the public.

(1) Fire extinguishers are conveniently located on each floor of the facility and in areas of special hazard. Fire regulations and fire management procedures are prominently posted and properly followed.

(2) All electrical and other equipment used in the facility is maintained free of defects which could be a potential hazard to patients or personnel. There is established a planned program of preventive maintenance of equipment used in dialysis and related procedures in the facility.

(3) The areas used by patients are maintained in good repair and kept free

of hazards such as those created by damaged or defective parts of the building.

(4) The facility is equipped with an alternate electrical power source provided by an emergency generator located on the premises to supply electrical power necessary in the event the normal electrical supply is interrupted. The emergency electrical power system supplies power adequate to maintain the operation of the dialysis machines and other life-support systems, for lighting in all means of egress, and equipment to maintain fire detection, alarm, and extinguishing systems.

(5) Water used for dialysis purposes is analyzed periodically and treated as necessary to maintain a continuous water supply that is biologically and chemically compatible with acceptable dialysis techniques. Records of test results and equipment maintenance are maintained at the facility.

(6) Electrical circuits serving all medical equipment in the dialysis facility or center are provided with 5 milliampere ground-fault interruptors.

(b) *Standard: favorable environment for patients.* The facility is maintained and equipped to provide a functional, sanitary, and comfortable environment with an adequate amount of well-lighted space for the services provided.

(1) There are written policies and procedures in effect for preventing and controlling hepatitis and other infections. These policies include, but are not limited to, appropriate procedures for surveillance and reporting of infections, housekeeping, handling and disposal of waste and contaminants, and sterilization and disinfection, including the sterilization and maintenance of equipment.

(2) Treatment areas are designed and equipped to provide adequate and safe dialysis therapy, as well as privacy and comfort for patients. The space for treating each patient is sufficient to accomodate medically needed emergency equipment and staff and to ensure that such equipment and staff can reach the patient in an emergency.

(3) There is provided a nursing/monitoring station from which adequate surveillance of patients receiving hemodialysis services can be made.

(4) Heating and ventilation systems are capable of maintaining adequate and comfortable temperatures.

(5) Each ESRD facility utilizing a central-batch delivery system provides, either on the premises or through affiliation agreement or arrangement (see §405.2160) sufficent individual delivery systems for the treatment of any patient requiring special dialysis solutions.

(c) *Standard: contamination prevention.* The facility employs appropriate techniques to prevent cross-contamination between the unit and adjacent hospital or public areas including, but not limited to, food service areas, laundry, disposal of solid waste and blood-contaminated equipment, and disposal of contaminants into sewage systems. Waste storage and disposal are carried out in accordance with applicable local laws and accepted public health procedures.

(d) *Standard: emergency preparedness.* Written policies and procedures specifically define the handling of emergencies which may threaten the health or safety of patients. Such emergencies would exist during a fire or natural disaster or during functional failures in equipment. Specific emergency preparedness procedures exist for different kinds of emergencies. These are reviewed and tested at least annually and revised as necessary by, or under the direction of, the chief executive officer. All personnel are knowledgeable and trained in their respective roles in emergency situations.

(1) There is an established written plan for dealing with fire and other emergencies which, when necessary, is developed in cooperation with fire and other expert personnel.

(2) All personnel are trained, as part of their employment orientation, in all aspects of preparedness for any emergency or disaster. The emergency preparedness plan provides for orientation and regular training and periodic drills for all personnel in all procedures so that each person promptly and correctly carries out a specified role in case of an emergency.

(3) There is available at all times on the premises a fully equipped emergency tray, including emergency drugs, medical supplies, and equipment, and staff are trained in its use.

(4) The staff is familiar with the use of all dialysis equipment and procedures to handle medical emergencies.

§ 405.2160 Condition: affiliation agreement or arrangement.

(a) A renal dialysis facility and a renal dialysis center (see § 405.2102(e)(2)) have in effect an affiliation agreement or arrangement with each other, in writing, for the provision of inpatient care and other hospital services.

(b) The affiliation agreement or arrangement provides the basis for effective working relationships under which inpatient hospital care or other hospital services are available promptly to the dialysis facility's patients when needed. The dialysis facility has in its files documentation from the renal dialysis center to the effect that patients from the dialysis facility will be accepted and treated in emergencies. There are reasonable assurances that:

(1) Transfer or referral of patients will be effected between the renal dialysis center and the dialysis facility whenever such transfer or referral is determined as medically appropriate by the attending physician, with timely acceptance and admission;

(2) There will be interchange, within 1 working day, of the patient long-term program and patient care plan, and of medical and other information necessary or useful in the care and treatment of patients transferred or referred between the facilities, or in determining whether such patients can be adequately cared for otherwise than in either of such facilities; and

(3) Security and accountability for patients' personal effects are assured.

§ 405.2161 Condition—Director of a renal dialysis facility or renal dialysis center.

Treatment is under the general supervision of a Director who is a physician. The physician-director need not devote full time as Director but is responsible for planning, organizing, conducting, and directing the professional ESRD services and must devote sufficient time to carrying out these responsibilities. The director may also serve as the Chief Executive Officer of the facility.

(a) *Standard: qualifications.* The director of a dialysis facility is a qualified physician-director. (See § 405.2102(r)(5))

(b) *Standard: responsibilities.* The responsibilities of the physician-director include but are not limited to the following:

(1) Participating in the selection of a suitable treatment modality, i.e., transplantation or dialysis, and dialysis setting, for all patients;

(2) Assuring adequate training of nurses and technicians in dialysis techniques;

(3) Assuring adequate monitoring of the patient and the dialysis process;

(4) Assuring the development and availability of a patient care policy and procedures manual and its implementation. As a minimum, the manual describes the types of dialysis used in the facility and the procedures followed in performance of such dialysis; hepatitis prevention and procedures for handling an individual with hepatitis; and a disaster preparedness plan (e.g., patient emergency, fire, flood); and

(5) When self-dialysis training is offered, assuring that patient teaching materials are available for patient use during training and at times other than during the dialysis procedure.

§ 405.2162 Condition: staff of a renal dialysis facility or renal dialysis center.

Properly trained personnel are present in adequate numbers to meet the needs of the patients, including those arising from medical and nonmedical emergencies.

(a) *Standard: registered nurse.* The dialysis facility employs at least one full time qualified nurse responsible for nursing service. (See § 405.2102(r)(4))

(b) *Standard: on-duty personnel.* Whenever patients are undergoing dialysis, other than self-care dialysis, one currently licensed health professional (e.g., physician, registered nurse, or licensed practical nurse) experienced in rendering ESRD care is on duty to oversee ESRD patient care, and an adequate number of personnel are present to meet the needs of patients, and an adequate number of personnel are readily available to meet medical and nonmedical emergencies.

(c) *Standard: self-care dialysis training personnel.* If the facility offers self-care dialysis training, a qualified nurse is in charge of such training (see § 405.2102(r)(4)).

§ 405.2163 Condition: Minimal service requirements for a renal dialysis facility or renal dialysis center.

In addition to chronic maintenance dialysis, the facility provides adequate laboratory, social, and dietetic services as needed to meet the needs of the ESRD patient.

(a) *Standard: laboratory services.* The dialysis facility makes available laboratory services (other than the specialty of tissue pathology and histocompatibility testing), to meet the needs of the ESRD patient. Laboratory services are performed either by a Medicare-approved hospital or by a qualified Medicare-approved independent laboratory, except that hematocrit and clotting time, which the facility uses to monitor its patients' fluids incident to each dialysis treatment, may be performed by the dialysis facility's staff, who are qualified by education and experience to perform such duties, under the direction of a physician.

(b) *Standard: social services.* Social services are provided to patients and their families and are directed at supporting and maximizing the social functioning and adjustment of the patient. Social services are furnished by a qualified social worker (§ 405.2102(r)(6)) who has an employment or contractual relationship with the facility. The qualified social worker is responsible for conducting psychosocial evaluations, participating in team review of patient progress and recommending changes in treatment based on the patient's current psychosocial needs, providing casework and groupwork services to patients and their families in dealing with the special problems associated with ESRD, and identifying community social agencies and other resources and assisting patients and families to utilize them.

(c) *Standard: dietetic services.* Each patient is evaluated as to his nutritional needs by the attending physician and by a qualified dietitian (§ 405.2102(r)(2)) who has an employment or contractual relationship with the facility. The dietitian, in consultation with the attending physician, is responsible for assessing the nutritional and dietetic needs of each patient, recommending therapeutic diets, counseling patients and their families on prescribed diets, and monitoring adherence and response to diets.

(d) *Standard: self-care dialysis support services.* The renal dialysis facility or center furnishing self-care dialysis training upon completion of the patient's training, makes available as appropriate (either directly, under agreement or by arrangement with another ESRD facility) the following services:

(1) Surveillance of the patient's home adaptation, including provisions for visits to the home or the facility;

(2) Consultation for the patient with a qualified social worker and a qualified dietitian;

(3) A record-keeping system which assures continuity of care;

(4) Installation and maintenance of equipment;

(5) Testing and appropriate treatment of the water; and

(6) Ordering of supplies on an ongoing basis.

(e) *Standard: participation in recipient registry.* The dialysis facility or center participates in a patient registry program for patients who are awaiting cadaveric donor transplantation.

§ 405.2170 Condition: Director of a renal transplantation center.

The renal transplantation center is under the general supervision of a qualified transplantation surgeon (§ 405.2102(r)(7)) or a qualified physician-director (§ 405.2102(r)(5)), who need not serve full time. This physician is responsible for planning, organizing, conducting, and directing the Renal Transplantation Center and devotes sufficient time to carry out these responsibilities, which include but are not limited to the following:

(a) Participating in the selection of a suitable treatment modality for each patient.

(b) Assuring adequate training, of nurses in the care of transplant patients.

(c) Assuring that tissue typing and organ procurement services are available either directly or under arrangement.

(d) Assuring that transplantation surgery is performed under the direct supervision of a qualified transplantation surgeon.

§ 405.2171 Condition: minimal service requirements for a renal transplantation center.

Kidney transplantation is furnished directly by a hospital which is participating as a provider of services in the Medicare program and is approved by the Secretary as a Renal Transplantation Center. The Renal Transplantation Center is under the overall direction of a hospital administrator and medical staff; if operated by an organizational subsidiary, it is under the direction of an administrator and medical staff member (or committee) who are directly responsible to the hospital administrator and medical staff, respectively. Patients are accepted for transplantation only on the order of a physician and their care continues under the supervision of a physician.

(a) *Standard: participation in recipient registry.* The Renal Transplantation Center participates in a patient registry program for patients who are awaiting cadaveric donor transplantation.

(b) *Standard: social services.* Social services are provided to patients and their families and are directed at supporting and maximizing the social functioning and adjustment of the patient. Social services are furnished by a qualified social worker (§ 405.2102(r)(6)) who has an employment or contractual relationship with the facility. The qualified social worker is responsible for conducting psychosocial evaluations, participating in team review of patient progress and recommending changes in treatment based on the patient's current psychosocial needs, providing casework and groupwork services to patients and their families in dealing with the special problems associated with ESRD, and identifying community social agencies and other resources and assisting patients and families to utilize them.

(c) *Standard: dietetic services.* Each patient is evaluated as to his nutritional needs by the attending physician and a qualified dietitian (§ 405.2102(r)(2)) who has an employment or contractual relationship with the facility. The dietitian, in consultation with the attending physician, is responsible for assessing the nutritional and dietetic needs of each patient, recommending therapeutic diets, counseling patients and their families on prescribed diets, and monitoring adherence and response to diets.

(d) *Standard: laboratory services.* The renal transplantation center makes available, directly or under arrangements, laboratory services to meet the needs of ESRD patients. Laboratory services are performed in a laboratory facility approved to participate in the Medicare program and, for histocompatibility testing purposes, notwithstanding approval pursuant to Subpart J also meets § 405.1314(b)(13) and § 405.1317(a), (b)(2)(i) and (ii), (b)(4), and (b)(8), and (when services are furnished in the specialty of tissue pathology) § 405.1314(b)(8)(i) and § 405.1317(a) and (b)(6)(ii).

(1) Laboratory services for crossmatching of recipient serum and donor lymphocytes for preformed antibodies by an acceptable technique are available on a 24-hour emergency basis.

(2) Available laboratory services also include:

(i) Suitable maintenance of recipient sera and typing regeants;

(ii) Phenotyping for donors and recipients;

(iii) Updating and retyping for HL–A and better defined antigens as indicated;

(iv) Screening of recipient sera for preformed antibodies with a suitable lymphocyte panel;

(v) Testing such as the mixed lymphocyte cultures to determine cellularly-defined antigens; and

(vi) ABO blood grouping and Rh typing.

(e) *Standard: organ procurement.* If a renal transplantation center utilizes the services of an organ procurement agency to obtain donor organs, it has a written arrangement covering these services. The renal transplantation center agrees to notify the Secretary in writing within 30 days of the termination of such arrangements.

APPENDIX

Pursuant to § 405.2111 of this Subpart, the following are designated as End-Stage Renal Disease Network Areas:

ESRD NETWORK NO. 1

American Samoa
Guam
Hawaii
The Trust Territory of the Pacific Islands

ESRD NETWORK NO. 2

The State of Alaska
The State of Idaho
The State of Montana
The State of Oregon
The State of Washington

ESRD NETWORK NO. 3

The following counties in Northern California:

Alameda
Alpine
Amador
Butte
Calaveras
Colusa
Contra Costa
Del Norte
El Dorado
Fresno
Glenn
Humboldt
Lake
Lassen
Madera
Marin
Mariposa
Mendocino
Merced
Modoc
Mono
Monterey
Napa
Nevada
Placer
Plumas
Sacramento
San Benito
San Francisco
San Joaquin
San Mateo
Santa Clara
Santa Cruz
Shasta
Sierra
Siskiyou
Solano
Sonoma
Stanislaus
Sutter
Tehama
Trinity
Tuolumne
Yolo
Yuba

The State of Nevada excluding Clark county which is included in Network area 4.

ESRD NETWORK NO. 4

The following counties in Southern California:

Imperial
Inyo
Kern
Kings
Los Angeles
Orange
Riverside
San Bernardino
San Diego
San Luis Obispo
Santa Barbara
Tulare
Ventura

The following county in Southern Nevada:

Clark

ESRD NETWORK NO. 5

The State of Colorado

The State of Utah excluding the Navaho Reservation portion of San Juan County which is in Network area 6.

The State of Wyoming

The following counties in the State of Nebraska:

Banner
Box Butte
Cheyenne
Dawes
Deuel
Garden
Kimball
Morrill
Scotts Bluff
Sheridan
Sioux

ESRD NETWORK NO. 6

The State of Arizona
The State of New Mexico

The Navaho Reservation portion of San Juan County, Utah.

ESRD NETWORK NO. 7

The State of Minnesota
The State of North Dakota
The State of South Dakota

The following counties in the State of Michigan:

Alger
Baraga
Delta
Dickinson
Gogebic
Houghton
Iron
Keweenaw
Marquette
Menominee
Ontonagon
Schoolcraft

The following counties in the State of Wisconsin:

Ashland
Bayfield
Burnett
Douglas
Iron
Price
Sawyer
Washburn

ESRD NETWORK NO. 8

Composed of:

The State of Iowa

The State of Nebraska excluding the following counties which are included in Network area 5:

Banner
Box Butte
Cheyenne
Dawes
Deuel
Garden
Kimball
Morrill
Scotts Bluff
Sheridan
Sioux

The following counties in the State of Illinois:

Henry
Mercer
Rock Island

ESRD NETWORK NO. 9

The State of Kansas

The State of Missouri excluding the following counties which are included in Network area 18:

Dunklin
Mississippi
New Madrid
Pemiscot
Scott
Stoddard

The following counties in the State of Illinois:

Clinton
Madison
Monroe
St. Clair

ESRD NETWORK NO. 10

The State of Arkansas excluding the following counties which are included in Network area 18:

Crittenden
Mississippi

The State of Oklahoma

ESRD NETWORK NO. 11

The State of Texas

ESRD NETWORK NO. 12

The State of Louisiana

ESRD NETWORK NO. 13

The State of Wisconsin excluding the following counties which are included in Network area 7:

Ashland
Bayfield
Burnett
Douglas
Iron
Price
Sawyer
Washburn

ESRD NETWORK NO. 14

The State of Michigan excluding the following counties which are included in network area number 7.

Alger
Baraga
Delta
Dickinson
Gogebic
Houghton
Iron
Keweenaw
Marquette
Menominee
Ontonagon
Schoolcraft

ESRD NETWORK NO. 15

The State of Illinois excluding the following counties which are included in Network area 8:

Henry
Mercer
Rock Island

and the following counties which are included in Network area 9:

Clinton
Madison
Monroe
St. Clair

ESRD NETWORK NO. 16

The State of Indiana

ESRD NETWORK NO. 17

The State of Kentucky

The following counties in the State of Ohio:

Adams
Brown
Butler
Champaign
Clark
Clermont
Clinton
Darke
Greene
Hamilton
Highland
Miami
Montgomery
Preble
Shelby
Warren

ESRD NETWORK NO. 18

The State of Alabama excluding the following county which is included in network area number 20.

Russell

The State of Mississippi
The State of Tennessee

The following counties in the State of Arkansas:

Crittenden
Mississippi

The following counties in the State of Georgia:

Catoosa
Dade
Walker

The following counties in the State of Missouri:

Dunklin
Mississippi
New Madrid
Pemiscot
Scott
Stoddard

The following counties in the State of Virginia:

Scott
Washington

ESRD NETWORK NO. 19

The State of Florida

ESRD NETWORK NO. 20

The State of Georgia excluding the following counties which are included in network area number 18.

Catossa
Dade
Walker

The State of South Carolina

The following county in the State of Alabama:

Russell

ESRD NETWORK NO. 21

The State of North Carolina

ESRD NETWORK NO. 22

Composed of the State of Ohio excluding the following counties which are included in network area number 17.

Adams
Brown
Butler
Champaign
Clark
Clermont
Clinton
Darke
Greene
Hamilton
Highland
Miami
Montgomery
Preble
Shelby
Warren

The following counties of Western Pennsylvania:

Allegheny
Armstrong
Beaver
Bedford
Blair
Butler
Cambria
Cameron
Clarion
Crawford
Elk
Erie
Fayette
Forest
Fulton
Greene
Huntingdon
Indiana
Lawrence
McKean
Mercer
Potter
Somerset
Venango
Warren
Washington
Westmoreland

ESRD NETWORK NO. 23

The District of Columbia.

The following counties in the State of Virginia:

Arlington
Fairfax
Loudoun
Prince William

The following counties in the State of Maryland:

Calvert
Charles
Montgomery
Prince Georges
St. Mary's

ESRD NETWORK NO. 24

The State of Delaware

The following counties of Eastern Pennsylvania:

Adams
Berks
Bucks
Carbon
Centre
Chester
Clearfield
Clinton
Columbia
Cumberland
Dauphin
Delaware
Franklin
Jefferson
Juniata
Lackawanna
Lancaster
Lebanon
Lehigh
Luzerne
Lycoming
Mifflin
Monroe
Montgomery
Montour
Northampton
Northumberland
Perry
Pike
Philadelphia
Schuylkill
Snyder
Union
Wayne
Wyoming
York

ESRD NETWORK NO. 25

The following counties of Metropolitan New York:

Bronx
Dutchess
Kings
Nassau
New York
Orange
Putnam
Queens
Richmond
Rockland
Suffolk
Sullivan
Ulster
Westchester

ESRD NETWORK NO. 26

The State of New York excluding the following counties which are included in Network area 25:

Bronx
Dutchess
Kings
Nassau
New York
Orange
Putnam
Queens
Richmond
Rockland
Suffolk
Sullivan
Ulster
Westchester

The following counties in the State of Pennsylvania:

Bradford
Susquehanna
Sullivan
Tioga

ESRD NETWORK NO. 27

The State of Connecticut

ESRD NETWORK NO. 28

The State of Maine
The State or Massachusetts
The State of New Hampshire
The State of Rhode Island
The State of Vermont

ESRD NETWORK NO. 29

Puerto Rico
Virgin Islands

ESRD NETWORK NO. 30

The State of Virginia excluding the following counties which are included in Network area 18:

Scott
Washington

and the following counties which are included in Network area 23:

Arlington
Fairfax
Loudoun
Prince William

The State of West Virginia

ESRD NETWORK NO. 31

The State of Maryland excluding the following counties which are included in Network area 23:

Calvert
Charles
Montgomery
Prince Georges
St. Mary's

ESRD NETWORK NO. 32

The State of New Jersey

[FR Doc.76-15924 Filed 6-2-76;8:45 am]

M-1

ESRD CHART EVALUATION

I **ESRD Schema:** ~~20% sample~~ of target (center based dialysis) population between 7/1/76 and 7/1/77

1) What is the code number of the Patient 1 C S L

2) What is the pt.'s age? 4 6 3

3) What is the underlying cause of the Pt.'s renal failure, if determinable? diabetes 6 I

4) How long has the pt. had ESRD (in mos)? 8 0 1

5) Is pt. in ESRD program? 11 1 0

A ESRD screening prospective dialysis pts.

6) Does the medical record indicate that the pt. has "permanent" or "irreversible" renal failure or "ESRD"? (the term chronic will not suffice) 13 1

yes=1 no=2

7) Prior to the assumption of maintenance dialysis, the medical record documents a 14 2

1=creatinine clearance less than 5 ml/min
2=serum creatinine greater than 10 mg/100ml
3=neither
4=unavailable

8) At the onset of dialysis which of the following does the medical record document as collaborative evidence of the indication for dialysis? (note if none documented leave blank 15 0 7

1=poor nutritional state	7=unsatisfactory control of CHF
2=nausea and vomiting	8=unsatisfactory control of bone disease
3=intractible itching	9=pericarditis
4=cerebral dysfunction	10=intractible fatigue or weakness
5=clinically symptomatic	11=several of the above
6=unsatisfactory control of hypertension	

9) Is there a note by a physician or a consent form which indicates that the pt/family have been informed of the options? 17 1

yes=1 no=2 unavailable=3

10) Is there a note by a physician or a consent form which indicates that the pt./family have been informed of realistic expectations? 18 1

yes=1 no=2 unavailable=3

11) Is there a note by a physician or a consent form (signed by pt or family) which indicates that the pt./family has accepted treatment? 19 1

yes=1 no=2 unavailable=3

12) Is there an initial psychiatric evaluation re: the suitability of pt for dialysis? 20 2

yes=1 no=2 unavailable=3

13) is there an initial Social Worker evaluation of pt.'s family/home situation as it impacts on pts. suitability for dialysis?
yes=1 no=2 unavailable=3

21 1

14) Is there an initial pre-dialysis nursing evaluation of the pt?
yes=1 no=2 unavailable=3

22 1

15) When was the last noted comprehensive nursing evaluation of the pt.'s status in mos?

23 0 5 6

16) Is there an initial evaluation by a dietician re: the pt.'s dietary management on dialysis?
yes=1 no=2 unavailable=3

27 1

17) When was the last noted comprehensive dietary evaluation of the pt. by a dietician (in mos).

28 7

B Should pt. be considered for renal transplantation

18) Is there a written statement by a physician that the pt. is medically suitable for transplantation?
yes=1 no=2 unavailable=3

29 2

19) Is there a note by a physician or his designee that the pt. is psychologically suitable for transplantation?
yes=1 no=2 unavailable=3

30 2

20) Is there a note that a nephrologist has presented the option of transplantation and discussed its risks with the pt.?

31 2

21) If the pt. elects transplantation, is there a referral to a transplant surgeon in writing?
yes=1 no=2 unavailable=3

32 -

22) Which of the following is indicated as a contraindication for transplantation?
1=active infection
2=oxalosis
3=malignancy (active past yr.)
4=uncontrolled hypertension
5=active peptic disease
6=a contraindication listed by the transplant surgeon to whom pt. is referred
7=pt refused surgery
8=unavailable

33 -

C. Selection of pts. for home dialysis

23) Has the pt. been advised of his option to dialyze at home?
yes=1 no=2 unavailable=3

34 2

24) If pt. elects to dialyze at home is he scheduled or being trained for home dialysis?
yes=1 no=2 unavailable=3

35 -

25) Which of the following does the chart indicate as exclusion from home dialysis?
1=pt. does not have willing or suitable partner
2=Pt. does not have adequate space or facilities
3=pt has unstable medical condition
4=pt scheduled for living donor transplant in next 6 mos
5=physician disapproved pt. as candidate for home dialysis
6=several of the above

36 7

25) 7=unavailable 8=no reason

26) If pt. is presently on center based dialysis but was on home dialysis, how long has pt. been on center based dialysis? 37

1=0-6mos
2=6mos-1yr
3=1 yr up to 18 mos
4=18mos up to 3yrs
5=2-3yrs
6=3 up to 4yrs
7=4yrs up to 5 yrs
8=5 or more yrs
9=unavailable

27) What is the reason for the pt.'s return to center based dialysis? 38 — —

28) If pt. is on center based dialysis and has never been on home dialysis, how long has pt. been on center based dialysis? 40 3

1=0-6mos
2=6mos up to 1yr
3=1yr up to 18mos
6=3 up to 4yrs
7=4 up to 5yrs
8=5 or more yrs
9=unavailable

D Hemodialysis Blood Studies To Aid in the Evaluation of Dialysis Outcome Performed between 6/76-6/77

29) How often was Pt. dialyzed? 41 8

1=less than 2/wk
2=twice/wk
3=3/wk
4=4/wk
5=5times/wk
6=6/wk
7=7/wk or more
8=unavailable

30) How often was pt.'s Hgb or Hct. drawn? 42 2

1=greater than once a wk
2=once/wk
3=once every 2 wks.
4=every 3 wks.
6=every 2 months
7=less often than every two mos.
8=undeterminable or irregularly
9=unavailable

31) On how many ocassions was pt. transfused? 43 1 1

1=once
2=twice
3=3times
4=4times
5=5 times
6=6 times
7=seven times
8=8times
9=9times
10=10 or more times
11=unavailable

32) Did pt.'s body weight fluctuate by more than ±5% of ideal body weight is determined by a physician? 45 3

yes=1 no=2 unavailable=3

33) Did the pt. experience severe symptomatic hypotension during or post dialysis(e.g. Syncope, Systolic BP less than 60 mm Hg)? 46 3

Yes=1 no=2 unavailable=3

34) Does the Chart contain diet order stating protein, sodium potassium and fluid allowances? 47 3

yes=1 no=2 unavailable=3

35) Does the chart contain a note by a registered dietician that the pt. has been instructed in his/her diet? 48 3

36) How often was pt.'s Ca and PO_4 drawn?
1=greater than once/wk
2=once/wk
3=once every two wks.
4=once every 3 wks.
5=once a month
6=every two mos
7=every three mos.
8=less often than every 3 mos.
9=unavailable

49 ☐ 9

37) How often was alkaline phosphatase drawn?
1=greater than once/wk
2=once/wk
3=every 2 wks
4=once a month
5=once every 6 wks.
6=every 2 months
7=every 3 mos.
8=Less frequently than every 3 mos.
9=unavailable

50 9

38) Did the pt. show an increase in alk. phosphatase greater than 50% in the past 12 months?
yes=1 no=2 unavailable=3

51 3

39) Did the pt. have any bone fractures?
yes=1 no=2 unavailable=3

52 3

40) How often was potassium drawn?
1=greater than once wkly
2=wkly
3=every 2 wks
4=every 3 wks
5=every 4 wks
6=every 5 wks
7=every 6 wks
8=every 2 mos
9=less frequently than every 2 mos
10=unavailable

53 10

41) How frequently was Bun and Creatinine drawn?
1=wkly
2=every 2 wks
3=every 3 wks
4=every month
5=every 5 wks
6=every 6 wks.
7=every 7 wks.
8=every 8 wks
9=less frequently than every 2 mos
10=unavailable

55 10

42) How frequently was a CBC drawn?
1=wkly
2=every 2 wks
3=every 3 wks
4=every 4 wks
5=every 5 wks
6=every 6 wks
7=every 7 wks
8=every 8 wks
9=every 9 wks
10=every 10 wks
11=every 11 wks.
12=every 12 wks
13=less frequently than every 12 wks
14=unavailable

57 14

43) How frequently was a platelet count drawn?
1=wkly
2=every 2 wks
3=every 3 wks
4=every 4 wks
5=every 5 wks.
6=every 6 wks
7=every 7 wks
8=every 8 wks.
9=every 9 wks.
10=every 10 wks
11=every 11 wks
12=every 12 wks
13=less frequently than every 12 wks
14=unavailable.

59 14

44) How frequently was Sgot/Sgpt drawn?

44) 1=wkly
2=every 2 wks
3=every 3 wks
4=every 4 wks
5=every 5 wks
6=every 6 wks
7=every 7 wks
8=every 8 wks
9=every 9 wks
10=every 10 wks
11=every 11 wks
12=every 12 wks
13=less frequently than every 12 wks
14=unavailable

61 1 1

45) How often was Australia Antigen drawn on pts.?
1=wkly
2=every 2 wks
3=every 3 wks
4=every 4 wks
5=every 5 wks
6=every 6 wks
7=every 7 wks
8=every 8 wks
9=every 9 wks
10=every 10 wks
11=every 11 wks
12=every 12 wks
13=less frequently than every 12 wks
14=unavailable

63 1 4

46) How many episodes of hepatitis did the pt have?
1=none
2=one
3=two
4=three
5=four
6=five
7=six or more
8=unavailable

65 8

47) How often was serum iron drawn?
1=every 2 wks
2=every 4 wks
3=every 6 wks
4=every 2 mos
5=every 10 wks
6=every 3 mos
7=every 14 wks
8=every 16 wks
9=every 18 wks
10=unavailable

66 1 0

48) How often was iron binding capacity drawn?
1=every 2 wks
2=every month
3=every 6 wks
4=every 2 mos
5=every 10 wks
6=every 3 mos
7=every 14 wks
8=every 16 wks
9=every 18 wks
10=unavailable

68 1 0

49) How often were serum electrolytes drawn? (Na, K, Cl, HCo_3)
1=every 2 wks
2=every month
3=every 6 wks
4=every 2 mos
5=every 10 wks
6=every 3 mos
7=every 14 wks
8=every 16 wks
9=every 18 wks
10=unavailable

70 1 0

50) How often was the serum Mg drawn?
1=every month
2=every 2 months
3=every 3 months
4=every 4 months
5=every 5 months
7=every 7 months
8=every 8 months
9=every 9 months or more
10=unavailable
11= none drawn

72 1 0

51) How often were triglycerides drawn?
1=every month
2=every 2 months
3=every 3 months
4=every 4 months
5=every 5 months
6=every 6 months
7=every 7 months
8=every 8 months
9=every 9 months
10=less than yrly
11=unavailable
12=none drawn

74 1 1

52) How often was serum cholesterol drawn?

1=every month	7=every 7 months
2=every 2 months	8=every 8 months
3=every 3 months	9=every 9 months
4=every 4 months	10=every 10 months
5=every 5 months	11=unavailable
6=every 6 months	12=none drawn

76 | 1 | 1 |

53) How often was serum glucose drawn?

1=every month	7=every 7 months
2=every 2 months	8=every 8 months
3=every 3 months	9=every 9 months
4=every 4 months	10=every 10 months
5=every 5 months	11=less than or = yrly
6=every 6 months	12=unavailable

78 | 1 | 2 |

54) How often was PTH drawn?

1=every month	7=every 7 months
2=every 2 months	8=every 8 months
3=every 3 months	9=every 9 months
4=every 4 months	10=every 10 months
5=every 5 months	11=less or = to yrly
6=every 6 months	12=unavailable

80 | 1 | 2 |

55) Is the pt a diabetic?
yes=1 no=2

82 | 1 |

56) How many times was pt seen by a psychiatrist in this period?

83 | 0 | 3 |

57) When was the pt last seen by a psychiatrist (in mos)?

85 | 1 | 5 | 0 |

58) How many times was the pt seen by a Social Worker in this period?

88 | — | — |

59) When was the pt.'s last S.W. consultation/notes (in mos)?

90 | — | — | — |

60) How often was pt seen by a dietician in this period?

93 | . | — |

61) When was the last noted dietary consultation (in mos)?

95 | — | — | — |

62) How often was the pt. seen by a nephrologist in this period?

98 | — | — |

63) When is the pt.'s last note by a nephrologist (in mos)?

100 | — | — | — |

64) What is the code # of the facility.

| 0 | 2 |

65) What is the sex of the pt.

| 1 |

66) What is the pt's ethnicity?

| 5 |

M-2

DRAFT

Dear Dr :

The final phase of the End Stage Renal Disease grant by the Connecticut Regional Medical Program was to assist the newly found network in the development of methodologies to measure the quality of medical care in the various stations.

Such assistance should be directed toward testing at least one approach to such measurement and of identifying more specific areas where in depth peer review should be undertaken.

Mr. Michael Owens, a fourth year medical student at Yale, has been devoting considerable time to this program with consultation with Dr. Finkelstein.

The methodology to be tested is based on the process of care patients in ESRD are receiving in Connecticut. It was necessary, therefore, to obtain from physicians, treatment protocols which would give some fix on what diagnostic tests and treatment procedures the patients should receive. The second part of the report, then, will compare these standards with a sample of patient charts in order to determine compliance with recognized criteria for high quality care.

What is now required is the completion of the attached protocol by Mr. Owens on a sample of patients under care at your hospital or station. Mr. Owens will contact you in the near future in order to arrange for such data gathering.

No patient, physician, or station will be identified in the report of this phase. The purpose of the study is not to measure the quality of care, but to test a methodology for such measurement. A complete report of the findings will be submitted to the network.

We would appreciate your cooperation in this endeavor and thus bring to a final closure the ESRD-CRMP grant.

Very truly yours,

Purchase Order M-3

YALE UNIVERSITY

B & F
2-7

PURCHASE ORDER
NO. 483819

THIS NUMBER MUST APPEAR ON ALL INVOICES, PACKAGES, PACKING SLIPS, & BILLS OF LADING

12/78

HAEL H. OWENS
DAGGETT ST.,
HAVEN, CONN. 06511

SHIP TO: YALE UNIVERSITY
SERV. PERFORMED
NEW HAVEN, CT.

BILL TO: (3 COPIES)
YALE UNIVERSITY
BOX 1301A YALE STA.
NEW HAVEN, CT. 06520

REPLY TO: G. TURNER
BOX 1501A, YALE STA., NEW HAVEN, CT.

VE AT YALE BY	SHIP VIA	F O B	TERMS
C'D		DEL.	N30

QUANTITY	UNIT	DESCRIPTION OF ITEMS AND/OR SERVICE	UNIT PRICE	% DISC
		TITLE 2 .. END STAGE RENAL DISEASE CRITERIA AND STANDARDS DEVELOPMENT. ESTIMATED TOTAL TIME - 500 HOURS. PURPOSE OF THE STUDY: 1. TO DEVELOP AN INSTRUMENTAL DATA ABSTRA-CT SHEET DERIVED FROM RECOMMENDED TESTS FOR PATIENTS WITH E.S.R.D. AND 2. TO TEST THIS INSTRUMENT AGAINST A SAMPLE OF E.S.R.D. CENTER BASED PATIENTS IN CONNECTICUT. SERVICES PERFORMED INVOICE ATTACHED. DATED 12/22/77	$800.00	

M-4

Yale University

INTER-OFFICE CORRESPONDENCE

Date: November 23, 1977

To: Francis L. Crowley

From: John D. Thompson

Subject: Mr. Michael Owens

Mr. Michael Owens is preparing a report on the ways of measuring the quality of patient care in the End Stage Renal Disease - Connecticut Network. This report was part of the original R.M.P. proposal. Mr. Owens was to be paid $1,000 for the report and started gathering data during the summer. This report will be due May 1978.

Since Mr. Owens has already incurred some expense in this endeavor, I would appreciate payment of 80 percent of the agreed upon fee at this time.

John D Thompson

JDT/my

cc: R. Simmons

M-3

Yale University

INTER-OFFICE CORRESPONDENCE

Date: March 30, 1977

To: Dr. Paul Doolan

From: Fredric O. Finkelstein, M. D.

Subject: Quality of Care

Quality of Care

The guidelines of the quality of care committee should provide the framework within which each unit can be reviewed. Each unit should be expected to define their basic medical practices to reviewing committees concerning the points listed below. The purpose of these guidelines is not to dictate practices, but to insure that each problem be dealt with in a consistent and reasonable fashion. Units should not be expected to file written reports, but just respond verbally during a site visit.

I. General Data

A. In-Center Hemodialysis

1) # patients treated

2) dialysis duration

a) times/week b) hrs./shift

3) equipment

4) pattern of nurses & technician staffing

B. Limited-care Hemodialysis

1) # patients treated

2) dialysis duration

a) times/week b) hrs./shift

3) equipment

4) pattern of nurses & technician staffing

C. In-Center Peritoneal Dialysis

1) # patients treated

2) dialysis duration

a) times/week b) hrs./shift

3) equipment

4) pattern of nurses & technician staffing

II. Home Hemodialysis Training

a) # beds allocated to home training

b) equipment used

c) dialysis duration and frequency

d) outline of training program and staffing patterns used

e) which patients are considered for home training

f) how are patients evaluated for home training

g) is it offered to all patients

h) how many patients has your unit tried to home-train

how many successfully dialyzed at home

how many successfully dialyzed at home and then returned to in-center dialysis

i) # patients home-trained last year

III. Home Peritoneal Training

a) # beds allocated to home training

b) equipment used

c) dialysis duration and frequency

d) outline of training program and staffing patterns used

e) which patients are considered for home training

f) how are patients evaluated for home training

g) is it offered to all patients

h) how many patients has your unit tried to home-train

how many successfully dialyzed at home

how many successfully dialyzed at home and then returned to in-center dialysis

i) # patients home-trained last year

IV. Candidates for chronic dialysis

- a) criteria for admission to dialysis program
- b) are any patients excluded from dialysis? If so, explain
- c) criteria for assignment to different treatment modalities
  - 1) hemodialysis, in-center
  - 2) hemodialysis, home
  - 3) hemodialysis, limited care
  - 4) peritoneal dialysis, in-center
  - 5) peritoneal dialysis, home

V. Mortality Rate

- a) # deaths during last year in different treatment modalities
  - 1) hemodialysis, in-center
  - 2) hemodialysis, home
  - 3) hemodialysis, limited care
  - 4) peritoneal dialysis, in-center
  - 5) peritoneal dialysis, home

VI. Problem Areas

- A. Osteodystrophy
  - 1) how is presence of checked for?
  - 2) treatment of:
    - a) clinical osteodystrophy
    - b) radiological osteodystrophy
    - c) no osteodystrophy

(details of use of phosphate binders, calcium concentrations and bath, use of vitamin D preparations, supplemental oral calcium, types of x-rays taken, criteria for interpretation of x-rays, use of bone biopsies)

B. Anemia

1) how is anemia evaluated

2) treatment

3) mean and ranges of Hct of patients

(details of folate and iron supplements, use of androgens evaluation of hemolysis, how frequently Hct's are checked, how iron deficiency is checked for)

C. Hypertension

1) evaluation

2) treatment

3) indications for nephrectomy

(details of blood pressure monitoring, use of antihypertensives).

D. Neuropathy

1) evaluation

2) treatment

(details of how neurological status is followed and what changes in management are recommended for patients with neuropathy)

E. Activity

a) what % of patients are working or in school?

full time
part time

b) % of patients in National Kidney Foundation functional classes

I________ II__________________ III___________ IV__________

F. Contamination

1) how and where are non-hepatitis infected patients dialyzed

2) Hepatitis

a) how often do you check for Australian antigen

b) do you have any patients or staff members with hepatitis

if yes, how have you dealt with the problem

if no, how would you deal with it.

3) have, or had any patient or staff member with hepatitis

how did you deal with this problem?

VII. Vascular Access

a) % patients with fistula
  1) wrist
  2) ankle
  3) antecubital
  4) other

b) % patients with shunts

c) % patients with grafts

VIII. Routine Laboratory Testing

IX. Transplantation

a) what patients are considered for transplantation

b) is transplantation offered to all patients

c) how many patients from unit have been transplanted

total last year

d) how many patients from unit are now on transplant list

e) to what transplant centers do you send your patients

f) what arrangements have been made for tissue typing.

M-6

Yale-New Haven Hospital
789 Howard Avenue • New Haven, Connecticut 06504

April 11, 1977

Paul Doolan, MD
St. Mary's Hospital
56 Franklin Street
Waterbury, Connecticut 06702

Dear Paul:

Enclosed, please find a copy of the optimal guidelines of practice for Nephrology Social Workers. This material is the result of a "brain storming", session we did as part of our agenda at our scheduled meeting held March 22, 1977, at St. Raphael's Hospital.

In our attempt to respond to the request of the Quality of Care Committee - we have tried to identify broad universal goals that can relate to all Connecticut Dialysis Units. Therefore, these guidelines are acceptable to all Connecticut Nephrology Social Workers at this time. More definitive definitions can be developed later if its mutually beneficial to the Social Workers and the network.

I have also enclosed a copy of the psycho-social data base. We hope to begin using this month. Where this information will be kept and how it will be shared with other dialysis staff members will be left to the judgment of each social worker, because communication patterns and unit structures are so diverse.

The Nephrology Dietitians of Connecticut also met recently and have compiled their optimal guidelines of practice. A copy is enclosed.

I look forward to our next Quality of Care Meeting.

Sincerely,

Jenny Kitsen

Jenny Kitsen
Social Worker-Dialysis

cc. Wendell Stevenson, Connecticut Kidney Foundation
920 Farmington Avenue
West Hartford, Connecticut 06107

Ms. Linda Press, Community Health Studies
60 College Street - LEPH 105
New Haven, Connecticut 06510

Quality of Care Subcommittee

The state department of health has standards for dialysis facilities. Ms. Swanson has recommended the standards developed by AANNT for hemodialysis, home training and peritoneal dialysis. They are thoughtful, responsible standards. Mrs. Kitsen and the social worker have also developed policies that assure us of the indicated support needed in this area. We have a number of outstanding dietitians in the state, more than one thoroughly acceptable manual for the ESRD patient and hence a solid competence in this area as well. Dr. Fred Finkelstein has submitted specific thought and/or comments on selection census, staffing, equipment and training. He has included the issues of mortality, vascular access, routine lab and transplantation as well as the problem areas of osteodystrophy, anemia, hypertension, neuropathy activity and contamination. Dr. John Maher has commented on many of the same matters and in addition ones that were of a more investigational nature such as mean generation times.

Related to but independent of the above efforts you have the long hard work of Drs. Grant and Silverman in Bridgeport and Dr. Gelfman in Danbury to develop information systems. The systems have not been designed for the same purpose one being patient and the other problem oriented. In addition to all of this we have the California guidelines.

There is therefore no lack of standards and criteria. The prudential course for this committee may be to simply sort out criteria, tabulate them and submit that to the MRC for their consideration. It may all come down to this anyway for these will be the realities of compliance with federal guidelines. The only additonal requirements would be to make some gestures on behalf of transplantation and peritoneal dialysis. If the coucil so wishes they can move to -

a. instruct the quality care committee to do this.
b. so instruct with the MRC members as a joint committee.

There is however some policy issues I would like to raise for consideration. One issue centers on computers and compliance while the related one has to do with audit. My preference would be for minimal stnadards and criteria and only the most epidemiological type of information for the computer. I am speaking in terms of a BP, wt, Hb, K and Cr, age, sex and dates. The emphasis would be on task forces that address themselves to specific problems such as -

1. How do you evaluate the BP?
2. What have autopsies on dialysis patients shown?
3. Which patients have done the best on dialysis and why?
4. What is the mortality?

Each of these questions involve other questions but the intention is to use them as examples. The social workers might wish to look at the percents working and dietitians might wish to examine the influence of drugs on appetite.

The contention is that addressing questions such as these would insure a meaningful involvement of more of the nephrologist and their colleagues; it would allow us to look at questions of our own choosing when we chose to do so; it would be a better learning experience than audit.

M-6

NEPHROLOGY SOCIAL WORKERS OF CONNECTICUT

In response to the request of the Quality of Care Committee of Network 27 - We the Nephrology Social Workers of Connecticut, have attempted to define basic guidelines for optimal professional practice. In order to define standards of practice we find it advantageous to focus on the following three broad categories. Patient-Team Member and Social Worker.

PATIENT:

1) Caseload: One full time social worker per 40 patients*, assuming availability of allied mental health professionals for consultation and/or services. Also reasonable geographic distribution of dialysis units, referral sources and patient population.

2) Referral to Social Services: Patients identified as dialysis candidates should be referred as soon as possible, no later than when vascular access is being discussed or considered.

3) Social Work Services to Patients:
   - a) Minimum direct patient contact-weekly
   - b) Opportunity for group approach as well as individual casework services
   - c) Family conferences with and without other team members
   - d) Home visits
   - e) Coordination of Community Resources

TEAM MEMBERS:

1) Social Worker to participate in patient care conference and goal setting.

2) Staff development: Social Worker should be available to staff for consultation and education.

3) Social Worker would participate in community education as a team member.

---

* Stated in tentative guidelines of National Council of Nephrology Social Workers.

SOCIAL WORKER:

1) Responsibility for providing psychosocial data base and ongoing case recording of significant information.

2) Availability of appropriate on site office for interviewing.

3) Opportunity for professional development attending workshops, conferences and continuing formal education. Encourage membership in Professional Organizations for mutual support and sharing of knowledge and experience.

Respectfully submitted,

N.S.W.C. Committee Members
Jenny Kitsen,
Yale-New Haven Hospital

Florence Kraut,
Norwalk Hospital

Diana Tomlin,
Bridgeport Hospital

M-6

NEPHROLOGY SOCIAL WORKERS OF CONNECTICUT

In response to the request of the Quality of Care Committee of Network 27 - We the Nephrology Social Workers of Connecticut, have attempted to define basic guidelines for optimal professional practice. In order to define standards of practice we find it advantageous to focus on the following three broad categories. Patient-Team Member and Social Worker.

PATIENT:

1) Caseload: One full time social worker per 40 patients*, assuming availability of allied mental health professionals for consultation and/or services. Also reasonable geographic distribution of dialysis units, referral sources and patient population.

2) Referral to Social Services: Patients identified as dialysis candidates should be referred as soon as possible, no later than when vascular access is being discussed or considered.

3) Social Work Services to Patients:
   a) Minimum direct patient contact-weekly
   b) Opportunity for group approach as well as individual casework services
   c) Family conferences with and without other team members
   d) Home visits
   e) Coordination of Community Resources

TEAM MEMBERS:

1) Social Worker to participate in patient care conference and goal setting.

2) Staff development: Social Worker should be available to staff for consultation and education.

3) Social Worker would participate in community education as a team member.

---

* Stated in tentative guidelines of National Council of Nephrology Social Workers.

M-7

GUIDELINES FOR NUTRITIONAL CARE OF ESRD PATIENTS

Dietitian is responsible for:

1. Initial assessment of nutritional status with recommendations for dietary management. This process involves identifying problems and resources, determining patient needs and evaluating ability to learn and attitude toward dietary management.
2. Documented evidence of nutrition education and follow-up compatible with patient's ability to learn. This process must include planned opportunities for patients to demonstrate, in a measurable way, their understanding of dietary management.
3. Intervention when nutritional goals are not met to an acceptable degree. This should be judged on basis of recognized nutritional recommendations for ESRD patients, the policies of the ESRD facility and individual patient situation.
4. * Follow-up assessment at least every three months.

Respectfully submitted by:

Committee of Nephrology Dieticians

Jacquelyn S. Cost, R.D.
Veterans Administration Hospital
West Haven, Conn.

Ethel Hall, R.D.
St. Raphael's Hospital
New Haven, Conn.

Mary H. Misiasek, R.D.
St. Mary's Hospital
Waterbury, Conn.

Mary Jane Halliday, R.D.
Danbury Hospital
Danbury, Conn.

Betty Schmitt, R.D.
Yale-New Haven, Hospital
New Haven, Conn.

M-8

THE ROLE OF THE SOCIAL WORKER
IN THE HEMODIALYSIS UNIT

POPULATION:

As of 4/4/77, 9 patient, 8 on Hemodialysis, and I, on peritonial dialysis.

FREQUENCY OF SOCIAL WORK CONTACT:

Worker makes daily rounds.

ROLE OF SOCIAL WORKER IN DIALYSIS UNIT:

The role of the social worker in the dialysis unit is to assess the psychosocial needs of the patients and their families and to help meet these needs. Also, the worker tries to be involved with other nephrology social workers so as to enhance her professional expertise and thus, enhance quality of care to her patients.

PSYCHOLOGICAL DIMENSION:

Along the Psychological Dimension, the worker assists the patient and his family in adjusting to the patient's renal disease. She helps the patient and family to cope with the life style changes that might occur as the patient starts dialysis and encourages the patient and family to interact with each other and within the community as closely to their former life style as before the onset of dialysis treatment.

SOCIAL DIMENSION:

Along the Social Dimension, the worker assists the patient in securing the financial and social services that he is entitled to and that are needful for him. This involves overseeing that the patient receives adequate insurance coverage, this often involving Medicare and State Welfare services, and also involves arranging for all other community services; for example, transportation and vocational counseling, that the patient requires in order that his life-style can be as normal and rewarding as possible with chronic renal failure.

COMMUNITY CONTACT:

A dialysis social worker needs contact with other dialysis

social workers in order to share professional expertise in order to enhance quality care towards the patient and his family.

One such outlet for this is the Counsel of Nephrology Social Workers. This is an organization founded in 1973 with the primary purpose of: 1. professional on-going education and sharing of information and to comment upon and recommend legislation regarding social services and 2. to serve in an advisory capacity to the National Kidney Foundation and the other organizations of the social work profession, and on the psychosocial issues and problems that confront kidney patients.

The local chapter of the CNSW consists of all renal social workers in Connecticut and meets approximately once monthly. The last meeting of which was held on 3/22/77 at St. Raphael's Hospital in New Haven, Connecticut. The agenda at that meeting involved finalizing the final revisions of the social service record, a social service form especially drafted by this chapter for use in the dialysis unit to be kept in the patient's chart.

M-9

UNIVERSITY OF CONNECTICUT
LTH CENTER

March 14, 1977

Dr. Paul Doolan
St. Mary's Hospital
56 Franklin Street
Waterbury, CT 06702

Dear Paul:

The enclosed comments or rather series of questions are intended to help survey the quality of medical care of maintenance dialysis patients.

Excluded are considerations of monitoring, e.g. for air embolism or dialyzer leaks. Other pertinent exclusions assumed to be covered elsewhere are as follows: Are all patients seen by a dietician, are all encouraged to home dialysis, etc.

If the council wants, there is extensive information available from the Monterrey Conference and the Boston study, but as they could easily dismiss these, I do not favor so lengthy a report.

With best wishes,

Sincerely yours,

John F. Maher, M.D.
Professor of Medicine
Director, Division of Nephrology

JFM:ajl

Enclosure

HOOL OF MEDICINE
MINGTON, CONNECTICUT 06032

In assessing the quality of medical care provided for maintenance dialysis patients, the following should be considered.

How is hemodynamic status evaluated? During dialysis, what assessment is made to anticipate and recognize volume depletion and how is it managed? What is done to evaluate recurring hypotension and how is it prevented? How is persistent hypertension evaluated and managed? How often are the end organ effects of hypertension, e.g. heart, retina evaluated? Is there evidence that uremic cardiopathy is sought regularly? What cardiovascular drugs are given? N.I

When pruritis occurs, what is done? When a skin rash is recognized, how is it evaluated?

How is mental function assessed and how often? How is peripheral nerve function assessed? What is done if abnormalities are found? How often is a neurological exam performed?

How is the gastrointestinal tract assessed and how often? What assessment of dietary intake is made? What is the mean net urea generation rate of the patients? How often are serum proteins measured and what fraction of patients have low values? Are vitamins prescribed routinely and if not, how is deficiency excluded?

How often is anemia assessed and what is mean hematocrit of the population? How often are transfusions given. Is iron supplementation routine and if not, how is deficiency excluded? What is the indication for more thorough investigation of anemia and what fraction of patients have been so investigated? How is the incidence of abnormal bleeding assessed? How is bleeding investigated?

What measures are used to prevent local infection. Is body temperature taken routinely, on suspicion, or never? Is white cell count measured periodically?

What assessment is made of bone disease? What is the incidence of hyperparathyroidism, of osteodystrophy? How often are bone radiographs done? What bath calcium is prescribed? Has dialysate water been tested for calcium or deionized? Has the water supply been tested for trace metals?

Have serum lipids been measured on the patients? Is there an assessment of endocrine abnormalities?

What is the mean clearance of patients starting dialysis? How often is NJ clearance measured in nephric patients? What is the mean clearance of patients 1 to 2 years after starting dialysis?

HEMODIALYSIS BLOOD STUDIES

WEEKLY -

Hct - 1/2 cc pedi lavender tube (if done in unit)
1 cc pedi lavender tube (if sent to lab)
Ca+PO_4 - 2 cc pedi red top tube -on patients newly started on DHT & Calcium until Ca & PO_4 stabilize
Glucose - 2 cc grey top tube -on insulin dependent diabetics

EVERY DIALYSIS -

Hct - If evidence of falling Hct - 1/2 cc pedi lavender (in unit)
1 cc pedi lavender (in lab)
Potassium - If K^+ greater than 6 meg/L - 2 cc pedi red top
Glucose - During regulation of insulin dose - 2 cc gray top tube

EVERY 2 WEEKS -

Potassium

MONTHLY -

Bun
Creatinine
Ca + PO_4
Alk. phosphatase
SGOT
Australian Antigen
} 1 full large red top tube
1 full pedi red top tube

CBC
Platelet count
} 1 full pedi lavender tube

QUARTERLY -(JANUARY, APRIL, JULY, OCTOBER)

Iron
Iron Binding Capacity
Complete Electrolytes:
- BUN
- Cr
- Na
- Cl
- K^+
- HCO_3
- Ca
- PO_4

Alk. Phosphatase
SGOT
} 2-1/2 large red top tubes

Australian Antigen - 1 full pedi red top
CBC
Platelet count
} 2 cc pedi lavender

SEMI-ANNUALLY - (JANUARY AND JUNE)

Magnesium
Triglycerides
Cholesterol
} 3 large red tops
Glucose - 2 cc gray top tube

PTH LEVEL : 1 Full red top tube on ice. Bring immediately to lab.

M-11

Hepatitis Screening of Patients

All new patients prior to admission to unit must have bloods drawn for

1. Australian antigen
2. SGOT

All patients must have blood drawn monthly for

1. Australian antigen
2. SGOT

If SGOT is elevated, complete liver function tests must be drawn.

If Australian antigen is positive after repeat, patient and all equipment used on patient must be isolated. Hospital administration must be informed in order to arrange isolation facilities.

M-12

Danbury Hospital the community health center
Danbury, Connecticut 06810 Telephone 203-797-7000

June 2, 1977

Mr. Royal A. Crystal
ESRD Program Director
Room 16A-16
5600 Fishers Lane
Rockville, Maryland 20857

Re: NCC #27 RESPONSE TO THE CALIFORNIA REGIONAL MEDICAL PROGRAM PROJECT REPORT.

Dear Mr. Crystal:

In response to your request of April 20, 1977, I would like to submit the formal comments of NCC #27 in regards to the California Regional Medical Program Project Report. In reviewing this document you requested feedback on both its usefulness and clarity. Our response will consist of both general comments and specific remarks by council members and staff.

Reviewing the California RMP project provided an interesting framework to begin the formulation of our needs for a quality of care review system for Connecticut. It is evident that the California project was a substantial undertaking which required a Task Force, an interdisciplinary staff, and considerable fiscal resources. It is clear that many Networks will not have similar resources available to develop such a comprehensive review system in a short time period. Never-the-less, we think that it is critical to the meaningful interest and co-operation of our member units that a program such as the California project be developed onsite in the respective networks with the full participation of their members. (Please see attachments A & B) Therefore, we are in agreement with the conclusion of the Task Force which stresses the necessity for locally developed criteria as a basis for the Medical Review Board functions. We also concur with the need for MRB unanimity in the criteria setting process.

In considering the informational needs of the Medical Review Board we agree with the Task Force's recommendation that local augmentation of the National ESRD Medical Information System is essential to a successful quality of care review system. Over the past two years we have developed a registry of our units and patients which will provide the basis for local implementation. This process is

commented on by our Information Coordinator, Mrs. Margaret Dunnington in Attachment "C". Our basic data collection instrument and a model study are also enclosed for your information and review.

At this time we visualize a staff component which will consist of an Executive Director, a part-time health professional, whose sole responsibility will be to the MRB, and our present information coordinator. We view this staffing pattern as the necessary core for optimal NCC and MRB functioning. The initial fiscal appropriation will be sufficient with the addition of local RMP monies for our first year of operations. This assessment is based on the fact that computer time has been donated on an in-kind basis. We would anticipate that additional monies maybe necessary to support our commitment to information and data gathering on a local level in our second year of operation.

In regards to the relevance of specific criteria sets we submit the following suggestions. Many of the proposed criteria sets will best achieve the goal of physician commitment and interest in quality of care review through a methodological approach which is based on diagnostic-specific criteria. For example, the events that pre-determine the decision to dialyze are different in the following diagnostic groups: Hypertension, Diabetes Mellitus, Polycystic kidney Disease, Glomerulonephritis. Similarly the incidence of complicating conditions such as anemia, hypertension, and bone disease have different disease prevalences. The patient mix of the unit with respect to age, sex and race will also influence applicability of certain criteria.

The application of different methodological approaches in some areas of quality of care review would seem to be desirable. For example, an on-site survey by an interdisciplinary team to a transplant unit may actually result in more effective patient care monitoring than solely relying on a statistical review as described in Criteria Sets #15 and 18. To achieve the goal of maintaining and/or improving the quality of patient care a combination of methodological approaches would appear to be necessary.

In utilizing Criteria Sets #10 and #11 a balanced approach to measuring the quality of dialysis would also include a measurement of a patients' activity level and overall well being. Our experience indicates that some of the most reliable indicators of quality of care can be summarized by the following points:

Kar [illegible] Scale

1. The patient's actual ability to perform his/her activities of daily living.
2. The subjective sense of well being which a patient expresses during an individual dialysis treatment.

The differences in respective unit's equipment and procedures must also be considered as these differences will effect such indicators as average pre-dialysis BUN values. For example, the use of the Redy system or the single needle method may be associated with higher BUN values. The uniform application of normative chemical indices potentially inhibits the essential individualization of the care giving process. The art of dialysis is an evolving one in which the optimum dialysis schedule and equipment (hardware) choices are not yet clear. It is important that a medical review system not prematurely inhibit continued experience with different treatment approaches.

In closing we would like to concur in the Advisory Council recommendation that the Bureau of Quality Assurance further fund the demonstration project in Northern California to complete an audit cycle in order to determine whether this type of audit criteria does improve the quality of patient care. Perhaps the BQA would consider funding a second project here in Connecticut where we already have a registry in place and where the predominate setting of dialysis differs significantly from northern California.

Sincerely yours,

Nelson A. Gelfman

Nelson A. Gelfman, M.D.
Chairman, Connecticut Network Coordinating
Council #27

NAG/du
attachments enclosed

ATTACHMENT "A"

TO: Mr. Royal A. Crystal
ESRD Program Director
Room 16A-16
5600 Fishers Lane
Rockville, Maryland 20857

FROM: Mrs. Jennie Kitsen
Hemodialysis Unit
Social Worker
Yale New-Haven Hospital

RE: Response to California Regional Medical Program Project Report.

GENERAL REMARKS

I. I realize the study for California limits age (16-55) and only Medicare patients to one year post-transplant follow up, but it seems that important information should be kept on patients of all ages in order to learn about these patients. There should also be long-term follow-up on all transplant patients regardless of the Medicare payment structure.

II. It would appear to be necessary to adapt criteria and threshold action to fit the differences in each Network. Around the country geographic, population, socio-cultural differences should be considered in criteria development. For example, perhaps the percentage of patients in the inner-city who are able to perform home dialysis is less than a middle class area.

III. The need for flexibility in criteria application and development should be recognized.

IV. It is suggested that staff in each dialysis and transplant unit be trained to retrieve information from patient's charts for MRB audit procedures. Would monies be available to pay for training and staff time? How much time would actually be needed to abstract said information?

V. I am in agreement with the statement that any adopted criteria or audit system must be agreed on by all professionals.

SPECIFIC REMARKS

I. CRITERIA SET #18
In regards to the rehabilitation status of transplant patients the issue of the number of patients who are capable of work but unable to gain employment must be considered. How would you define these individuals rehabilitation status?

II. CRITERIA SET #4.
I feel that a Social Worker should be an inherent part of the evaluative work-up of both the transplant patient and the living related donor.

III. CRITERIA SET #8 - TRANSPLANT.
The feasibility of a Social Worker being able to realistically evaluate the rehabilitation status of post-transplant patients within the first two months should be examined. For those patients with medical complications this time frame may be unrealistic. It is suggested that a psycho-social and rehabilitation assessment is an important component of the transplant process.

IV. CRITERIA SET #9 - TRANSPLANT.

In addition to the Social Worker evaluating a patient's psycho-social status at least once, the patient's rehabilitation status should also be a component of the Social Work assessment. It is my experience that the most successful transplant patients are able to return to work within the first year.

V. CRITERIA SET #5.

This criteria set on Home Dialysis seems to allow no choice on the patient's part to decline going home if he wishes to remain in a unit setting. The whole question of freedom of treatment choice is an obvious issue. The question of the patient's reason for refusing home dialysis on the grounds of excess cost must also be considered. The California experience may be that local or state funds are available to pick-up the 20% deductible which is not covered by Medicare. In Connecticut a patient's personal insurance must cover the costs. However, many private insurance policies do not provide this coverage.

VI. CRITERIA SET #13.

The importance of adequate Social Service follow-up of Home Dialysis should be included.

VII. CRITERIA SET #25.

The stated criteria are presently included in the data base which has been developed by the Nephrology Social Workers of Connecticut. (Copy attached).

VIII. CRITERIA SET #26.

These criteria are reasonable and are included in the Connecticut Nephrology Social Work Recommendations. However, I have some concern about the phrase "when requested." This term suggests that we cannot see all new dialysis patients and that we must wait for a referral from a physician or nurse. I would hope that this would not be an operational problem in Conn. It is my thought that all physicians have enough respect and understanding to realize the need for all patients to be seen at least once by a Social Worker. At Yale and many other units in the state I know that it is assumed that all patients will be seen by a Social Worker.

IX. CRITERIA SET #27,

I know that these topics are discussed with some patients in our units. The availability of Social Work time in some units in Connecticut is a major problem which also makes documentation in patients charts a problem. The importance of good-record-keeping procedures should be noted.

X. CRITERIA SET #28.

A six to twelve month follow-up time frame is reasonable as a standard. In many units it is done more frequently. The need for information in the first three months of dialysis should be addressed with the mechanism for obtaining this information from the patient's family. The rationale for interviewing the family is that the patient is frequently too sick or stressed for in-depth interviewing by a Social Worker.

5/25/77
du

ATTACHMENT "B"

Yale University *New Haven, Connecticut*

SCHOOL OF MEDICINE
333 Cedar Street
Department of Internal Medicine

(4U)

May 31, 1977

Nelson Gelfman, M. D.
Interim Chairman
Network Coordinating Council
ESRD Program

Dear Dr. Gelfman:

At the request of your ESRD quality of care Committee, I have reviewed the file report of the project to develop model criteria and standards for care of end stage renal disease patients developed in California in July 1976. " It appears to me that two major comments need be made concerning this project and its possible applicability to end stage renal failure programs in Connecticut. First and most importantly, the criteria established for this California group may not be directly applicable to care in the Connecticut area. Criteria for review of several medical problems, including transplantation, anemia, selection of patients for home dialysis, and others differ in some respects from what I would consider optimal criteria in Connecticut." For this reason, it would appear to me that we would need to recommend our own criteria for such medical review. Secondly, it is clear from the size and comprehensive nature of the report concerning criteria and standards that a considerable amount of effort will be required both to establish and to maintain in a practical way these criteria of care.

If I can be afforded more time to carefully review this document, I could specifically tell you in each area how my recommendations for review might differ from those established by the California group.

Sincerely,
AS Kliger
Alan S. Kliger, M. D.
Asst. Professor of Medicine

/am

cc: Paul Doolan, Chairman
Quality of Care Committee

ATTACHMENT "C"

Gil

TO: Nelson A. Gelfman, M.D.
Chairman, Network Coordinating Council #27
Danbury Hospital
95 Locust Avenue
Danbury, Connecticut 06810

FROM: Mrs. Margaret Dunnington
Connecticut Hemodialysis Registry Information Coordinator
30 Boulder Hill Road
Ridgefield, Connecticut 06877

RE: RESPONSE TO CALIFORNIA AUDIT PROJECT ref: LOCAL ADAPTATION.

I. TWO ESRD REGULATIONS WILL MOTIVATE PARTICIPATION IN LOCAL AUDIT STUDIES:

a. that facilities must participate in at least one medical care evaluation study; (e.g., audit)

b. that Medical Review Boards must use data from ESRD/MIS OR their own criteria and standards or both to evaluate appropriateness of treatment modalities for patients (ref: transplants);

II. LOCAL IMPLEMENTATION MIGHT MINIMIZE TWO OF THE MAJOR CALIFORNIA PROBLEMS:

a. TIME: Majority of the 10 months' project life was spent training for audit and decreasing resistance of a selected group of varied professionals prior to initiating studies.

Since then, the federally mandated networks are "in the works" so a nucleus may already be formed to approve criteria sets.

Also, the "ground work" of methodology and, in many instances, quite simple criteria sets, already developed might be adapted in a short time. ESRD/MIS regulations may define immediate areas for audit/study.

b. AUTHORITY: California's grantee/study project had no authority to assure responses.

Connecticut, as a network, might endorse the studies/audits and thus have the power to ensure responses.

The Registry experience has been 100% response (finally included two units which needed repeated prodding) on a voluntary program, indicating that the unit directors were "sold" on the registry through their professional associations.

(note: Since the March 21 printout was mailed to units, continuous input has been received from 10 of the 15 units without further follow-up.)

OPINION: If the requests for additional data are simple, clear, and minimal (most units do not have clerks to do the enormous volume

of paperwork) and if the requesting body have the authority of a NCC or MRB, responses should be forthcoming.

III. THE CURRENT REGISTRY ALREADY MEETS MANY OF THE CALIFORNIA RECOMMENDATIONS:

a. Our input forms elicit recorded facts (not judgements) which increase reliability.

b. A non-medical person can abstract and transfer to computer sheets.

c. In most units, the same individual does all that unit's reporting and is the contact person for the Registry Aide.

d) "Better documentation leads to better care": Our Registry combines into a single printout information about each invividual patient not available in a single source in most units.

IV. FEASIBILITY OF USING CALIFORNIA CRITERIA SETS:

a) The Registry does not presently elicit all of the data in their Criteria Sets.

Several could be obtained if there is unit staff or project staff to abstract from our 495+ patient files: social worker contacts; selection for transplant; option for home dialysis; transplant survival.

b.) Our chemistry data does not coincide with either their renal osteodystrophy or anemia criteria sets. Lab results giving this data are probably reported in the unit files; however, obtaining them would necessitate a series of monthly or bimonthly reports and would require a commitment of staff time at each unit. The reporting forms could be simply designed.

(NOTE: this non-medical person cannot judge whether or not the California criteria chemistries might already be in our Anemia Study (copy enclosed). Computer space is already programmed locally for hemoglobin and hematocrit, so these could be studied if units are willing to supply the values for several weeks or months.)

c. A study of transplants appears to be needed: this Registry Aide did not observe much documentation in patient files about previous transplants, duration, etc. We are not requesting this data in the new Patient History Form, however, we are developing a file of patients transplanted since our first complete Registry in March, 1976. The California report noted that the national registry does not follow up transplants past 12 months.

V. POSSIBLE IMPLEMENTATION OF AN AUDIT/STUDY PROJECT UTILIZING OUR REGISTRY:

a. INITIATION: studies, and the criteria objectifying them, should be initiated by an existing "authority" group such as the NCC or MRB.

b. IMPLEMENTATION: A staff person "Coordinator" could then carry out the following tasks: work with computer programmer to translate requested studies into programs; develop forms for inputs from units and forms for computer inputs;

communicate authorized requests to units;
receive responses and follow-up nonrespondents;
transfer to computer forms;
coordinate with computer programmer

- check output for accuracy; resubmit omissions and errors send feedback to units; be available for questions from units; be available for questions from units; prepare analysis for authority group.

The California project recommends that data be supplied from units; this seems advisable to protect confidentiality of patient records and accuracy of data.

To facilitate the various stages of the project, a single individual should fulfill both coordination and clerical roles, have overall knowledge of the project.

If the authorizing group feels it is necessary, the coordinator could also collect the data from the units. (but not recommended)

It would appear to be optimal that unit staff work in conjunction with the information coordinator in the data collection process.

VI. OPERATIONAL REQUIREMENTS:

a. A central communication center for: files, sending and receiving mail, sending and receiving telephone communications.

This could be shared space, although work area and typewriter availability would be necessary.

Access to computer facility.

Equipment: typewriter (paper, carbon, ribbons, etc.), mailing supplies (clasp envelopes, address labels) marking pens (for computer inputs) file folders, file drawers (currently four portable cardboard drawer/boxes are being used), desk or work table with supply drawer, telephone (shared), access to copier.

VII. COST ESTIMATES OF DATA COLLECTION:

a. As a rough measure of time/cost: Maintenance of Registry (after all units visited and registered) and preparation for updated March 21 printout - 68 hours: December, Jan., Feb., and March = $204.00 wages.

Special project (changing the program for 500 patients: involved consultation with programmers, redesigning and typing both the unit input form and the computer input form, and recategorizing primary diseases and complicating conditions for all patients, entering the new codes for the computer) - 35 hours: December, Jan., Feb. = $105.00 wages

Because of the time log of the incumbent was not complete, a Coordinator should be planned for at least 15 - 20 hours a week; more, of course, if it is necessary to obtain data from the units.

Expenses during the time this Aide has been working with the Registry (November, 1975 through December, 1976) - $ 76.85 (primarily mailing costs & gas - .15/mile) There has been no expense for duplicating hundreds of pages of forms, some mailings done through the Hospital), typewriter and supplies, phone service, or office space and equipment.

5/24/77

```
                                        FREQUENCY DISTRIBUTIONS

VAR(2)         PT AGE                   N=     50   MEAN=    49.080   MEDIAN=   51.500   SD=    13.195

   VALUE            18.000      19.000      24.000      26.000      27.000      28.000      32.000      34.000      35.000
   FREQUENCY             1           1           1           1           1           1           1           1           1
   PERCENTAGE        2.00%       2.00%       2.00%       2.00%       2.00%       2.00%       2.00%       2.00%       2.00%
   CUMULATIVE        2.00%       4.00%       6.00%       8.00%      10.00%      12.00%      14.00%      16.00%      18.00%

   VALUE            36.000      37.000      38.000      42.000      43.000      47.000      49.000      50.000      51.000
   FREQUENCY             1           1           1           1           2           3           1           4           2
   PERCENTAGE        2.00%       2.00%       2.00%       2.00%       4.00%       6.00%       2.00%       8.00%       4.00%
   CUMULATIVE       20.00%      22.00%      24.00%      26.00%      30.00%      36.00%      38.00%      46.00%      50.00%

   VALUE            52.000      53.000      54.000      55.000      56.000      57.000      58.000      59.000      62.000
   FREQUENCY             2           3           1           2           3           1           2           2           2
   PERCENTAGE        4.00%       6.00%       2.00%       4.00%       6.00%       2.00%       4.00%       4.00%       4.00%
   CUMULATIVE       54.00%      60.00%      62.00%      66.00%      72.00%      74.00%      78.00%      82.00%      86.00%

   VALUE            63.000      64.000      67.000      71.000      74.000
   FREQUENCY             1           2           2           1           1
   PERCENTAGE        2.00%       4.00%       4.00%       2.00%       2.00%
   CUMULATIVE       88.00%      92.00%      96.00%      98.00%     100.00%

VAR(3)         COUSE RENAL FAILURE      N=      0   MEAN=     0.0     MEDIAN=    0.0     SD=     0.0

   VALUE             BLANK
   FREQUENCY            50

VAR(4)         LENGTH ESRD IN MOS       N=     48   MEAN=    38.167   MEDIAN=   30.000   SD=    25.439

   VALUE            10.000      12.000      16.000      18.000      19.000      20.000      21.000      22.000      24.000
   FREQUENCY             1           1           1           4           2           1           1           3           5
   PERCENTAGE        2.08%       2.08%       2.08%       8.33%       4.17%       2.08%       2.08%       6.25%      10.42%
   CUMULATIVE        2.08%       4.17%       6.25%      14.58%      18.75%      20.83%      22.92%      29.17%      39.58%

   VALUE            26.000      27.000      30.000      31.000      32.000      33.000      34.000      35.000      36.000
   FREQUENCY             1           1           4           1           1           1           1           1           1
   PERCENTAGE        2.08%       2.08%       8.33%       2.08%       2.08%       2.08%       2.08%       2.08%       2.08%
   CUMULATIVE       41.67%      43.75%      52.08%      54.17%      56.25%      58.33%      60.42%      62.50%      64.58%

   VALUE            38.000      41.000      42.000      45.000      48.000      51.000      59.000      70.000      88.000
   FREQUENCY             1           3           2           1           1           2           1           1           1
   PERCENTAGE        2.08%       6.25%       4.17%       2.08%       2.08%       4.17%       2.08%       2.08%       2.08%
   CUMULATIVE       66.67%      72.92%      77.08%      79.17%      81.25%      85.42%      87.50%      89.58%      91.67%

   VALUE            95.000      96.000     115.000     120.000       BLANK
   FREQUENCY             1           1           1           1           2
   PERCENTAGE        2.08%       2.09%       2.08%       2.08%
   CUMULATIVE       93.75%      95.93%      97.92%     100.00%
```

```
VAR(6)          PERMANENT RENAL DISEAS    N=    50   MEAN=     1.240   MEDIAN=     1.000   SD=     0.472

    VALUE               1.000        2.000        3.000
    FREQUENCY              39           10            1
    PERCENTAGE         78.00%       20.00%        2.00%
    CUMULATIVE         78.00%       98.00%      100.00%

VAR(7)          BEFORE DIAL MR DOCUMENTS  N=    49   MEAN=     2.122   MEDIAN=     2.000   SD=     0.773

    VALUE               1.000        2.000        3.000        4.000       BLANK
    FREQUENCY               8           31            6            4           1
    PERCENTAGE         16.33%       63.27%       12.24%        8.16%
    CUMULATIVE         16.33%       79.59%       91.84%      100.00%

VAR(8)          COLL EVIDENCE DIALYSIS    N=    39   MEAN=     6.077   MEDIAN=     6.000   SD=     3.092

    VALUE               1.000        2.000        3.000        4.000        6.000        7.000        8.000        9.000       10.000
    FREQUENCY               1            8            1            4            6            9            1            1            3
    PERCENTAGE          2.56%       20.51%        2.56%       10.26%       15.38%       23.08%        2.56%        2.56%        7.69%
    CUMULATIVE          2.56%       23.08%       25.64%       35.90%       51.28%       74.36%       76.92%       79.49%       87.18%

    VALUE              11.000       BLANK
    FREQUENCY               5          11
    PERCENTAGE         12.82%
    CUMULATIVE        100.00%

VAR(9)          PT INFORMED OPTS BY DOC   N=    50   MEAN=     1.360   MEDIAN=     1.000   SD=     0.686

                          YES           NO      UNAVAIL

    VALUE               1.000        2.000        3.000
    FREQUENCY              38            6            6
    PERCENTAGE         76.00%       12.00%       12.00%
    CUMULATIVE         76.00%       88.00%      100.00%

VAR(10)         PT INFORMED REAL EXPECTS  N=    50   MEAN=     1.180   MEDIAN=     1.000   SD=     0.517

                          YES           NO      UNAVAIL

    VALUE               1.000        2.000        3.000
    FREQUENCY              44            3            3
    PERCENTAGE         88.00%        6.00%        6.00%
    CUMULATIVE         88.00%       94.00%      100.00%
```

```
                                              FREQUENCY DISTRIBUTIONS

VAR(11)          PT AND FAM ACCEPT DX      N=    50    MEAN=      1.200   MEDIAN=      1.000   SD=     0.566
                          YES           NO        UNAVAIL

     VALUE              1.000        2.000          3.000
     FREQUENCY             44            2              4
     PERCENTAGE        88.00%        4.00%          8.00%
     CUMULATIVE        88.00%       92.00%        100.00%

VAR(12)          INIT PSYCH EVALUATION     N=    50    MEAN=      2.020   MEDIAN=      2.000   SD=     0.547
                          YES           NO        UNAVAIL

     VALUE              1.000        2.000          3.000
     FREQUENCY              7           35              8
     PERCENTAGE        14.00%       70.00%         16.00%
     CUMULATIVE        14.00%       84.00%        100.00%

VAR(13)          INITIAL S W EVALUATION    N=    50    MEAN=      1.640   MEDIAN=      1.000   SD=     0.768
                          YES           NO        UNAVAIL

     VALUE              1.000        2.000          3.000
     FREQUENCY             27           14              9
     PERCENTAGE        54.00%       28.00%         18.00%
     CUMULATIVE        54.00%       82.00%        100.00%

VAR(14)          INIT PREDIAL NURS EVAL    N=    50    MEAN=      1.520   MEDIAN=      1.000   SD=     0.781
                          YES           NO        UNAVAIL

     VALUE              1.000        2.000          3.000
     FREQUENCY             33            8              9
     PERCENTAGE        66.00%       16.00%         18.00%
     CUMULATIVE        66.00%       82.00%        100.00%

VAR(15)          LAST COMP NURS EVAL MOS   N=    47    MEAN=      4.170   MEDIAN=      4.000   SD=     2.263
     VALUE              1.000        2.000          3.000       4.000       5.000       6.000       8.000       9.000      12.000
     FREQUENCY              3            6              9          18           3           2           2           3           1
     PERCENTAGE         6.38%       12.77%         19.15%      38.30%       6.38%       4.26%       4.26%       6.38%       2.13%
     CUMULATIVE         6.38%       19.15%         38.30%      76.60%      82.98%      87.23%      91.49%      97.87%     100.00%

     VALUE              BLANK
     FREQUENCY              3
```

FREQUENCY DISTRIBUTIONS

```
VAR(16)        INIT EVAL DIETICIAN        N=    50   MEAN=     1.580   MEDIAN=     1.000   SD=     0.896

                          YES           NO        UNAVAIL
   VALUE                 1.000        2.000        3.000        4.000
   FREQUENCY                33            7            8            2
   PERCENTAGE           66.00%       14.00%       16.00%        4.00%
   CUMULATIVE           66.00%       80.00%       96.00%      100.00%

VAR(17)        LAST COMP DIET EVAL        N=    40   MEAN=     3.275   MEDIAN=     3.000   SD=     1.962

   VALUE                 0.000        1.000        2.000        3.000        4.000        5.000        6.000        7.000        9.000
   FREQUENCY                 1            6            9            9            6            4            1            3            1
   PERCENTAGE            2.50%       15.00%       22.50%       22.50%       15.00%       10.00%        2.50%        7.50%        2.50%
   CUMULATIVE            2.50%       17.50%       40.00%       62.50%       77.50%       87.50%       90.00%       97.50%      100.00%
   VALUE                 BLANK
   FREQUENCY                10

VAR(18)        MED SUIT TRPLANT NOTE      N=    50   MEAN=     2.000   MEDIAN=     2.000   SD=     0.748

                          YES           NO        UNAVAIL
   VALUE                 1.000        2.000        3.000        4.000
   FREQUENCY                12           28            8            2
   PERCENTAGE           24.00%       56.00%       16.00%        4.00%
   CUMULATIVE           24.00%       80.00%       96.00%      100.00%

VAR(19)        PSYCH SUIT TRPLANT NOTE    N=    47   MEAN=     2.128   MEDIAN=     2.000   SD=     0.672

                          YES           NO        UNAVAIL
   VALUE                 1.000        2.000        3.000        4.000        BLANK
   FREQUENCY                 6           31            8            2            3
   PERCENTAGE           12.77%       65.96%       17.02%        4.26%
   CUMULATIVE           12.77%       78.72%       95.74%      100.00%
```

```
VAR(23)          PT ADVISED HOM DIAL OPT    N=    50   MEAN=      2.000   MEDIAN=      2.000   SD=      0.748
                         YES          NO       UNAVAIL
    VALUE               1.000       2.000       3.000      5.000
    FREQUENCY              11          30           8          1
    PERCENTAGE         22.00%      60.00%      16.00%      2.00%
    CUMULATIVE         22.00%      82.00%      98.00%    100.00%

VAR(24)          PT SCH OR TRAIN HOM DIAL   N=    18   MEAN=      2.556   MEDIAN=      2.500   SD=      0.831
                         YES          NO       UNAVAIL
    VALUE               1.000       2.000       3.000      5.000      BLANK
    FREQUENCY               1           8           8          1         32
    PERCENTAGE          5.56%      44.44%      44.44%      5.56%
    CUMULATIVE          5.56%      50.00%      94.44%    100.00%

VAR(25)          HOMDIAL EXCLU REASON       N=    43   MEAN=      3.558   MEDIAN=      3.000   SD=      2.424
                   NO PRTNER  SPACE FACIL  MD UNSTABLE  LIV REL DON    UNAVAIL
    VALUE               1.000       2.000       3.000      4.000       7.000      BLANK
    FREQUENCY              14           1          14          1          13          7
    PERCENTAGE         32.56%       2.33%      32.56%      2.33%      30.23%
    CUMULATIVE         32.56%      34.88%      67.44%     69.77%     100.00%
```

```
VAR(28)       PT LENGTH CBD ALONE       N=    49   MEAN=     5.347   MEDIAN=     5.000   SD=    1.944

                  6MOS-1YR   1YR-18 MOS  18MOS- 2 YR      2-3YR        3-4YR        4-5YR        GE 5 YR

    VALUE           2.000       3.000       4.000        5.000        6.000        7.000        8.000        9.000       BLANK
    FREQUENCY           1          10           7           10            9            2            6            4           1
    PERCENTAGE      2.04%      20.41%      14.29%       20.41%       18.37%        4.08%       12.24%        8.16%
    CUMULATIVE      2.04%      22.45%      36.73%       57.14%       75.51%       79.59%       91.84%      100.00%

VAR(29)       FREQUENCY PT DIAL         N=    50   MEAN=     3.560   MEDIAN=     3.000   SD=    1.538

                  TWICE WK    THRICE WK      4 A WK     UNAVAIL

    VALUE           2.000       3.000       4.000        8.000
    FREQUENCY           3          36           6            5
    PERCENTAGE      6.00%      72.00%      12.00%       10.00%
    CUMULATIVE      6.00%      78.00%      90.00%      100.00%

VAR(30)       FREQUENCY HGB OR HCT      N=    50   MEAN=     4.800   MEDIAN=     5.000   SD=    2.173

                  GR ONCE WK  ONCE A WK      E 2 WK      E 3  WK       E 5 WK    LT E 2 MO      UNAVAIL

    VALUE           1.000       2.000       3.000        4.000        5.000        7.000        9.000
    FREQUENCY           2           3          10            7           19            1            8
    PERCENTAGE      4.00%       6.00%      20.00%       14.00%       38.00%        2.00%       16.00%
    CUMULATIVE      4.00%      10.00%      30.00%       44.00%       82.00%       84.00%      100.00%

VAR(31)       TIMES PT TRANSFUSED       N=    45   MEAN=     4.467   MEDIAN=     2.000   SD=    4.500

                                ONCE           2            3            4            6            7            8        GE 10

    VALUE           0.000       1.000       2.000        3.000        4.000        6.000        7.000        8.000       10.000
    FREQUENCY           7          13           3            4            1            1            4            1            3
    PERCENTAGE     15.56%      28.89%       6.67%        8.89%        2.22%        2.22%        8.89%        2.22%        6.67%
    CUMULATIVE     15.56%      44.44%      51.11%       60.00%       62.22%       64.44%       73.33%       75.56%       82.22%

                  UNAVAIL

    VALUE          11.000      17.000       BLANK
    FREQUENCY           7           1           5
    PERCENTAGE     15.56%       2.22%
    CUMULATIVE     97.78%     100.00%
```

```
VAR(32)        5% FLUCT BODY WT           N=    49    MEAN=     2.122    MEDIAN=     2.000    SD=     0.520
                        YES           NO         UNAVAIL
                                                    FREQUENCY DISTRIBUTIONS

    VALUE              1.000         2.000         3.000         BLANK
    FREQUENCY              4            35            10             1
    PERCENTAGE         8.16%        71.43%        20.41%
    CUMULATIVE         8.16%        79.59%       100.00%

VAR(33)        DIAL CASH SYMP HYPOTEN     N=    50    MEAN=     1.900    MEDIAN=     2.000    SD=     0.53
                        YES           NO         UNAVAIL

    VALUE              1.000         2.000         3.000
    FREQUENCY             10            35             5
    PERCENTAGE        20.00%        70.00%        10.00%
    CUMULATIVE        20.00%        90.00%       100.00%

VAR(34)        DIET ORDER K NA FLU PRO    N=    50    MEAN=     1.620    MEDIAN=     1.000    SD=     1.075
                        YES           NO         UNAVAIL

    VALUE              1.000         2.000         3.000         7.000
    FREQUENCY             32             9             8             1
    PERCENTAGE        64.00%        18.00%        16.00%         2.00%
    CUMULATIVE        64.00%        82.00%        98.00%       100.00%

VAR(35)        NOTE PEG DIET PE PT DIET   N=    50    MEAN=     1.460    MEDIAN=     1.000    SD=     0.754
                        YES           NO         UNAVAIL

    VALUE              1.000         2.000         3.000
    FREQUENCY             35             7             8
    PERCENTAGE        70.00%        14.00%        16.00%
    CUMULATIVE        70.00%        84.00%       100.00%

VAR(36)        FREQ CA PO                 N=    50    MEAN=     5.160    MEDIAN=     5.000    SD=     1.912
                    ONC A WK       E 2 WK       E 3 WK         E MO       E 2 MOS       E 3MOS      UNAVAIL

    VALUE              2.000         3.000         4.000         5.000         6.000         8.000         9.000
    FREQUENCY              3             8             1            27             3             1             7
    PERCENTAGE         6.00%        16.00%         2.00%        54.00%         6.00%         2.00%        14.00%
    CUMULATIVE         6.00%        22.00%        24.00%        78.00%        84.00%        86.00%       100.00%

VAR(37)        FREQ ALK PHOS              N=    50    MEAN=     5.020    MEDIAN=     4.000    SD=     1.860
                      E 2 WK       E 3 WK         E MO       E 2 MOS        E3 MOS       E 3MOS      UNAVAIL

    VALUE              3.000         4.000         5.000         6.000         7.000         8.000         9.000
    FREQUENCY              2            33             2             3             2             1             7
    PERCENTAGE         4.00%        66.00%         4.00%         6.00%         4.00%         2.00%        14.00%
    CUMULATIVE         4.00%        70.00%        74.00%        80.00%        84.00%        86.00%       100.00%
```

```
VAR(38)       RISE ALK PHOS 50%      N=    50   MEAN=     2.060   MEDIAN=     2.000   SD=     0.465
                     YES           NO       UNAVAIL

   VALUE            1.000        2.000        3.000
   FREQUENCY            4           39            7
   PERCENTAGE       8.00%       78.00%       14.00%
   CUMULATIVE       8.00%       86.00%      100.00%

VAR(39)       PT HAVE BONE FRAX      N=    50   MEAN=     2.000   MEDIAN=     2.000   SD=     0.490
                     YES           NO       UNAVAIL

   VALUE            1.000        2.000        3.000
   FREQUENCY            6           38            6
   PERCENTAGE      12.00%       76.00%       12.00%
   CUMULATIVE      12.00%       88.00%      100.00%

VAR(40)       FREQUENCY K            N=    50   MEAN=     4.880   MEDIAN=     4.500   SD=     2.463
                    E WK       E 2 WK        E 3WK         E MO       E5 WK      UNAVAIL

   VALUE            2.000        3.000        4.000        5.000        6.000       10.000
   FREQUENCY            4           15            6           15            2            8
   PERCENTAGE       8.00%       30.00%       12.00%       30.00%        4.00%       16.00%
   CUMULATIVE       8.00%       38.00%       50.00%       80.00%       84.00%      100.00%

VAR(41)       FREQUENCY BUN CREAT    N=    50   MEAN=     4.560   MEDIAN=     4.000   SD=     2.570
                  E 2 WK       E 3 WK      E MONTH       E 5 WK       E 6 WK      UNAVAIL

   VALUE            2.000        3.000        4.000        5.000        6.000       10.000
   FREQUENCY           11            4           23            2            2            8
   PERCENTAGE      22.00%        8.00%       46.00%        4.00%        4.00%       16.00%
   CUMULATIVE      22.00%       30.00%       76.00%       80.00%       84.00%      100.00%

VAR(42)       FREQUENCY CBC          N=    50   MEAN=     5.300   MEDIAN=     4.000   SD=     4.487
                    WKLY       E 2 WK       E 3 WK         E4WK        E5 WK     E 10 WK      UNAVAIL

   VALUE            1.000        2.000        3.000        4.000        5.000       10.000       14.000       17.000
   FREQUENCY            4           11            3           19            3            1            8            1
   PERCENTAGE       8.00%       22.00%        6.00%       38.00%        6.00%        2.00%       16.00%        2.00%
   CUMULATIVE       8.00%       30.00%       36.00%       74.00%       80.00%       82.00%       98.00%      100.00%
```

FREQUENCY DISTRIBUTIONS

```
VAR(43)      FREQ PLATELET CT          N=    50   MEAN=     7.320   MEDIAN=     6.000   SD=     4.007

                        WKLY        E 2 WK        E 3 WK        E MO        E 5 WK        E 6 WK        E7 WK        E 2 MOS        E 10 WK
  VALUE                1.000        2.000         3.000        4.000        5.000         6.000        7.000         8.000         10.000
  FREQUENCY                1            2             1           14            3             7            3             5              2
  PERCENTAGE           2.00%        4.00%         2.00%       28.00%        6.00%        14.00%        6.00%        10.00%          4.00%
  CUMULATIVE           2.00%        6.00%         8.00%       36.00%       42.00%        56.00%       62.00%        72.00%         76.00%

                     E 3 MOS   LT E 3 MOS      UNAVAIL
  VALUE               12.000       13.000        14.000
  FREQUENCY                1            2             9
  PERCENTAGE           2.00%        4.00%        18.00%
  CUMULATIVE          78.00%       82.00%       100.00%

VAR(44)      FREQUENCY SGOT OR PT      N=    48   MEAN=     6.938   MEDIAN=     4.000   SD=     4.404

                      E 2 WK       E 3 WK          E MO       E 5 WK        E 6 WK        E7 WK       E 2 MOS        E 9 WK        E 3 MOS
  VALUE                2.000        3.000         4.000        5.000         6.000        7.000         8.000         9.000         12.000
  FREQUENCY                2            2            25            1             1            1             2             1              1
  PERCENTAGE           4.17%        4.17%        52.08%        2.08%         2.08%        2.08%         4.17%         2.08%          2.08%
  CUMULATIVE           4.17%        8.33%        60.42%       62.50%        64.58%       66.67%        70.83%        72.92%         75.00%

                     UNAVAIL
  VALUE               14.000        BLANK
  FREQUENCY               12            2
  PERCENTAGE          25.00%
  CUMULATIVE         100.00%

VAR(45)      FREQUENCY AA ON PTS       N=    50   MEAN=     6.280   MEDIAN=     4.000   SD=     3.985

                      E 3 WK         E MO        E 5 WK       E 6 WK        E 9 WK      E 11 WK       E 3 MOS       UNAVAIL
  VALUE                3.000        4.000         5.000        6.000         9.000       11.000        12.000        14.000
  FREQUENCY                4           28             4            2             1            1             1             9
  PERCENTAGE           8.00%       56.00%         8.00%        4.00%         2.00%        2.00%         2.00%        18.00%
  CUMULATIVE           8.00%       64.00%        72.00%       76.00%        78.00%       80.00%        82.00%       100.00%

VAR(46)      NUM EPISODES HEPATITIS    N=    49   MEAN=     2.163   MEDIAN=     1.000   SD=     2.582

                        NONE            1       UNAVAIL
  VALUE                1.000        2.000         8.000        BLANK
  FREQUENCY               40            1             8            1
  PERCENTAGE          81.63%        2.04%        16.33%
  CUMULATIVE          81.63%       83.67%       100.00%
```

```
VAR(47)         FREQUENCY SERUM FE          N=    50   MEAN=      8.080    MEDIAN=      9.000    SD=      2.505

                      E MO     E 2   MOS      E 10 WK      E 3 MOS      E 18 WK      UNAVAIL

    VALUE            2.000       4.000       5.000       6.000       9.000      10.000
    FREQUENCY            5           3           1           1          29          11
    PERCENTAGE      10.00%       6.00%       2.00%       2.00%      58.00%      22.00%
    CUMULATIVE      10.00%      16.00%      18.00%      20.00%      78.00%     100.00%

VAR(48)         FREQ FE BINDING CAPACITY    N=    50   MEAN=      8.180    MEDIAN=      9.000    SD=      2.551

                      E MO     E 2   MOS      E 10 WK      E 3 MOS      E 18 WK      UNAVAIL

    VALUE            2.000       4.000       5.000       6.000       9.000      10.000      11.000
    FREQUENCY            6           1           1           1          29          11           1
    PERCENTAGE      12.00%       2.00%       2.00%       2.00%      58.00%      22.00%       2.00%
    CUMULATIVE      12.00%      14.00%      16.00%      18.00%      76.00%      98.00%     100.00%

VAR(49)         FREQ ELECTROLYTES           N=    50   MEAN=      3.880    MEDIAN=      2.000    SD=      3.421

                    E 1 WK        E MO     E 2   MOS      E 10 WK      E 14 WK      E 4 MOS      E 18 WK      UNAVAIL

    VALUE            1.000       2.000       4.000       5.000       7.000       8.000       9.000      10.000
    FREQUENCY           10          24           2           1           1           1           2           9
    PERCENTAGE      20.00%      48.00%       4.00%       2.00%       2.00%       2.00%       4.00%      18.00%
    CUMULATIVE      20.00%      68.00%      72.00%      74.00%      76.00%      78.00%      82.00%     100.00%

VAR(50)         FREQ SERUM MG               N=    48   MEAN=      9.375    MEDIAN=     10.000    SD=      2.027

                     E MOS      E 6 MO       E 8 MO    E 9 MO LE     ~~UNAVAIL~~    ~~NON DRAW~~

    VALUE            1.000       6.000       8.000       9.000      10.000      11.000      12.000       BLANK
    FREQUENCY            1           6           1          14           8          17           1           2
    PERCENTAGE       2.08%      12.50%       2.08%      29.17%      16.67%      35.42%       2.08%
    CUMULATIVE       2.08%      14.58%      16.67%      45.83%      62.50%      97.92%     100.00%

VAR(51)         FREQ TRIGLYCERIDES          N=    50   MEAN=      9.980    MEDIAN=     10.000    SD=      2.131
                                                         < year       unavail
                    E 4 MO      E 6 MO    E 9 MO LE     ~~UNAVAIL~~    ~~NON DRAW~~

    VALUE            4.000       6.000       9.000      10.000      11.000      12.000
    FREQUENCY            1           7           7          11           8          16
    PERCENTAGE       2.00%      14.00%      14.00%      22.00%      16.00%      32.00%
    CUMULATIVE       2.00%      16.00%      30.00%      52.00%      68.00%     100.00%
```

FREQUENCY DISTRIBUTIONS

```
VAR(52)        FREQ SERUM CHOLESTEROL     N=    50,  MEAN=     10.260   MEDIAN=     11.000   SD=      1.958
                   F 6 MO      E 9 MO LE        ~~UNAVAIL~~     ~~NON DRAN~~

    VALUE          6.000        9.000        10.000       11.000       12.000
    FREQUENCY          7            3            14            8           18
    PERCENTAGE    14.00%        6.00%        28.00%       16.00%       36.00%
    CUMULATIVE    14.00%       20.00%        48.00%       64.00%      100.00%

VAR(53)        FREQ SERUM GLUCOSE         N=    50   MEAN=      6.280   MEDIAN=      5.000   SD=      4.147
                                E MOS        E 2 MO       E 3MO        E 4 MO       E 6 MO      ~~UNAVAIL~~    ~~NON DRAN~~

    VALUE          0.000        1.000         2.000        3.000        4.000        6.000       10.000       11.000       12.000
    FREQUENCY          1            6             3            4           11            8            2            2           13
    PERCENTAGE     2.00%       12.00%         6.00%        8.00%       22.00%       16.00%        4.00%        4.00%       26.00%
    CUMULATIVE     2.00%       14.00%        20.00%       28.00%       50.00%       66.00%       70.00%       74.00%      100.00%

VAR(54)        FREQUENCY PTH              N=    49   MEAN=      9.816   MEDIAN=     11.000   SD=      2.624
                   F 4 MO       F 6 MOS   LE F 10 MOS    NON DRAWN     UNAVAIL

    VALUE          4.000        6.000        10.000       11.000       12.000       17.000        BLANK
    FREQUENCY          2           10            11           14           11            1            1
    PERCENTAGE     4.08%       20.41%        22.45%       28.57%       22.45%        2.04%
    CUMULATIVE     4.08%       24.49%        46.94%       75.51%       97.96%      100.00%

VAR(55)        PT DIABETIC                N=    50   MEAN=      1.860   MEDIAN=      2.000   SD=      0.490
                     YES           NO

    VALUE          1.000        2.000         3.000
    FREQUENCY         10           37             3
    PERCENTAGE    20.00%       74.00%         6.00%
    CUMULATIVE    20.00%       94.00%       100.00%

VAR(56)        FREQ PSYCH CONSULT         N=    42   MEAN=      0.071   MEDIAN=      0.0      SD=      0.457
    VALUE          0.000        3.000         BLANK
    FREQUENCY         41            1             8
    PERCENTAGE    97.62%        2.38%
    CUMULATIVE    97.62%      100.00%
```

```
    VALUE              9.000       17.000       23.000       25.000       29.000       31.000          BLANK
    FREQUENCY              2            1            1            1            1            1              4
    PERCENTAGE         4.35%        2.17%        2.17%        2.17%        2.17%        2.17%
    CUMULATIVE        89.13%       91.30%       93.48%       95.65%       97.83%      100.00%

VAR(62)            FREQ NEPHRO CONSULT       N=    43    MEAN=     12.442    MEDIAN=    12.000    SD=      6.592

    VALUE              0.000        1.000        4.000        5.000        6.000        9.000       10.000       11.000       12.000
    FREQUENCY              1            2            4            1            2            1            4            1           12
    PERCENTAGE         2.33%        4.65%        9.30%        2.33%        4.65%        2.33%        9.30%        2.33%       27.91%
    CUMULATIVE         2.33%        6.98%       16.28%       18.60%       23.26%       25.58%       34.88%       37.21%       65.12%

    VALUE             15.000       17.000       18.000       19.000       20.000       21.000       25.000       26.000       27.000
    FREQUENCY              2            2            3            1            3            1            1            1            1
    PERCENTAGE         4.65%        4.65%        6.98%        2.33%        6.98%        2.33%        2.33%        2.33%        2.33%
    CUMULATIVE        69.77%       74.42%       81.40%       83.72%       90.70%       93.02%       95.35%       97.67%      100.00%

    VALUE              BLANK
    FREQUENCY              7

VAR(63)            LAST NEPHRO CONSULT MOS   N=    48    MEAN=      1.542    MEDIAN=     1.000    SD=      0.912

    VALUE              1.000        2.000        3.000        4.000        5.000        BLANK
    FREQUENCY             31           12            2            2            1            2
    PERCENTAGE        64.58%       25.00%        4.17%        4.17%        2.08%
    CUMULATIVE        64.58%       89.58%       93.75%       97.92%      100.00%

VAR(64)            FACILITY CODE             N=    50    MEAN=      2.920    MEDIAN=     3.000    SD=      1.906

    VALUE              1.000        2.000        3.000        4.000        5.000
    FREQUENCY             16            8            7           12            7
    PERCENTAGE        32.00%       16.00%       14.00%       24.00%       14.00%
    CUMULATIVE        32.00%       48.00%       62.00%       82.00%      100.00%

VAR(65)            SEX                       N=    50    MEAN=      1.480    MEDIAN=     1.000    SD=      0.500

                        MALE       FEMALE

    VALUE              1.000        2.000
    FREQUENCY             26           24
    PERCENTAGE        52.00%       48.00%
    CUMULATIVE        52.00%      100.00%

VAR(66)            ETHNIC ORIENTATION        N=    50    MEAN=      4.240    MEDIAN=     5.000    SD=      1.530

                     AFRO AM   LA SURNAME    CAUCASIAN

   VALUE              1.000        2.000        5.000
   FREQUENCY              8            2           40
   PERCENTAGE        16.00%        4.00%       80.00%
   CUMULATIVE        16.00%       20.00%      100.00%
```

FREQUENCY DISTRIBUTIONS

```
VAR(57)        LAST PSYCH CONSULT MOS     N=   41   MEAN=    5.293   MEDIAN=    0.0     SD=    16.696

   VALUE              0.000      4.000      34.000      40.000      61.000      78.000      BLANK
   FREQUENCY             36          1           1           1           1           1          9
   PERCENTAGE        87.80%      2.44%       2.44%       2.44%       2.44%       2.44%
   CUMULATIVE        87.80%     90.24%      92.68%      95.12%      97.56%     100.00%

VAR(58)        FREQ S W CONSULT           N=   42   MEAN=    5.881   MEDIAN=    3.500   SD=     6.196

   VALUE              0.000      1.000       2.000       3.000       4.000       5.000       6.000       8.000      10.000
   FREQUENCY             12          1           6           2           1           1           4           4           2
   PERCENTAGE        28.57%      2.38%      14.29%       4.76%       2.38%       2.38%       9.52%       9.52%       4.76%
   CUMULATIVE        28.57%     30.95%      45.24%      50.00%      52.38%      54.76%      64.29%      73.81%      78.57%

   VALUE             12.000     13.000      14.000      15.000      20.000      21.000      BLANK
   FREQUENCY              1          2           2           1           1           2          8
   PERCENTAGE         2.38%      4.76%       4.76%       2.38%       2.38%       4.76%
   CUMULATIVE        80.95%     85.71%      90.48%      92.86%      95.24%     100.00%

VAR(59)        LAST S W CONSULT MOS       N=   43   MEAN=    2.930   MEDIAN=    2.000   SD=     3.818

   VALUE              0.000      1.000       2.000       3.000       4.000       6.000       7.000       9.000      24.000
   FREQUENCY              8          8           9           2          12           1           1           1           1
   PERCENTAGE        18.60%     18.60%      20.93%       4.65%      27.91%       2.33%       2.33%       2.33%       2.33%
   CUMULATIVE        18.60%     37.21%      58.14%      62.79%      90.70%      93.02%      95.35%      97.67%     100.00%

   VALUE              BLANK
   FREQUENCY              7

VAR(60)        FREQ DIET CONSULT          N=   43   MEAN=    4.349   MEDIAN=    2.000   SD=     5.313

   VALUE              0.000      1.000       2.000       3.000       4.000       5.000       6.000       7.000       9.000
   FREQUENCY             12          5           5           3           2           3           4           1           1
   PERCENTAGE        27.91%     11.63%      11.63%       6.98%       4.65%       6.98%       9.30%       2.33%       2.33%
   CUMULATIVE        27.91%     39.53%      51.16%      58.14%      62.79%      69.77%      79.07%      81.40%      83.72%

   VALUE             10.000     12.000      15.000      16.000      25.000      BLANK
   FREQUENCY              2          2           1           1           1          7
   PERCENTAGE         4.65%      4.65%       2.33%       2.33%       2.33%
   CUMULATIVE        88.37%     93.02%      95.35%      97.67%     100.00%

VAR(61)        LAST DIET CONSULT MOS      N=   46   MEAN=    5.196   MEDIAN=    2.500   SD=     7.465

   VALUE              0.000      1.000       2.000       3.000       4.000       5.000       6.000       7.000       8.000
   FREQUENCY              6         11           6           3           7           3           1           1           1
   PERCENTAGE        13.04%     23.91%      13.04%       6.52%      15.22%       6.52%       2.17%       2.17%       2.17%
   CUMULATIVE        13.04%     36.96%      50.00%      56.52%      71.74%      78.26%      80.43%      82.61%      84.78%
```

YALE MEDICAL LIBRARY

Manuscript Theses

Unpublished theses submitted for the Master's and Doctor's degrees and deposited in the Yale Medical Library are to be used only with due regard to the rights of the authors. Bibliographical references may be noted, but passages must not be copied without permission of the authors, and without proper credit being given in subsequent written or published work.

This thesis by   has been used by the following persons, whose signatures attest their acceptance of the above restrictions.

NAME AND ADDRESS   DATE

1/79

John R. [illegible], 86 Springside Ave., New Haven 5/14/79

5/15/80

C.G. Wilkinson · 8 Marydale Rd. W.H. Ct. · 5/17/82